

DHEW HEALTH RESEARCH PRINCIPLES

Volume I

Documents Relating to the
Development of
Draft Health Research Principles
for the
Department of Health, Education, and Welfare

April - December 1978

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service National Institutes of Health

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Office of the Director
National Institutes of Health
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Bethesda, Maryland 20014

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April -- December 1978

Prepared by the
Office of the Director, NIH

DHEW Publication Number (NIH) 79-1890

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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Public Health Service National Institutes of Health

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INTRODUCTION

This Volume documents the major activities leading to the development of draft health research principles for the Department of Health, Education, and Welfare. It is the first in a series of projected documents which will together constitute a public record of the process used and the factors considered in formulating a multi-year strategy for health research conducted and supported by DHEW. This Volume covers the period from April, when Secretary Califano initiated a new, open process to develop a multi-year strategy for health research, through December 1978 with the completion of the Report of the National Conference on Health Research Principles.

This Volume is organized as follows:

- Section A reproduces the Conference Report which contains the revised draft DHEW health research principles;
- Section B includes the program and other documents describing the structure and content of the National Conference on Health Research Principles held at the National Institutes of Health on October 3-4, 1978;
- Section C provides a chronology of key events in the process with cross-references to specific documents contained in this Volume;
- Section D traces the process following the Department to formulate the draft statement of health research principles that was presented to participants of the National Conference for review and modification; and
- Section E documents the manner in which advice and participation in this process were solicited from other Federal Departments and agencies, members of Congress, international representatives, and the public. This Section also contains documents describing the involvement and roles of the Institute of Medicine, National Academy of Sciences and the five Conference Panels charged with receiving public testimony and revising and refining the draft DHEW statement of health research principles.

The three Appendices to this Volume provide further documentation of public participation in the development of draft DHEW health research principles. Appendix A lists the approximately 1,000 professional societies and health organizations that were invited to participate in the National Conference and asked for their views and suggestions on health research principles for the Department. Letters of comment received in response to this request

are reproduced in Appendix B. Appendix C contains copies of all public testimony considered in the development of the Report of the National Conference on Health Research Principles.

A second volume of the series is contemplated which will document major activities from the completion of the Conference Report through the adoption of final health research principles by the Department.

SECTION A

Report on the National Conference on Health Research Principles

In December, 1978, the attached Conference Report was sent to all Conference participants, organizations and individuals who had provided suggestions on the principles the Department should adopt, and others expressing interest in this DHEW initiative. Comments on the revised draft DHEW health research principles contained in the Conference Report were solicited as well as suggestions for specific health research goals based upon the principles. The Conference Report which was mailed to the participants contained two appendices -- the draft DHEW health research principles presented at the National Conference (reproduced in Section D of this Volume) and the roster of Panel membership (reproduced in Section E of this Volume).



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

December 18, 1978

MEMORANDUM TO: Participants in the Development of
Department of Health, Education, and Welfare
Health Research Principles

SUBJECT: Report on the National Conference on Health
Research Principles

On behalf of Secretary Califano and myself, I would like to express appreciation to each of you for the interest you have shown in the development of health research principles for the Department and the contributions you have made throughout this process. The views and concerns expressed at the National Conference, held at the National Institutes of Health on October 3 and 4, have moved us closer to the formulation of a set of principles to guide the development of a multi-year health research plan. Enclosed are the results of the deliberations of the Conference. We encourage you to share your views with us on the revised draft DHEW health research principles.

I am impressed with the Conference Panel reports and the revised principles which are based upon these reports and the testimony and suggestions provided by you. Your efforts have moved us ahead in this difficult task. Your comments on the enclosed report, coupled with the results of the evaluation of this report by the Institute of Medicine, National Academy of Sciences, will form the basis for the completion of this phase of the initiative; namely, the establishment of health research principles for DHEW.

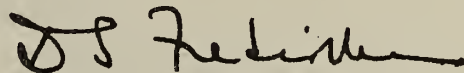
The next step in this initiative will be to spell out specific health research goals based upon the principles finally adopted. Once these goals have been identified, the task will be to translate them into a plan and budget by the Fall of 1979.

While the revised research principles enclosed are still subject to possible changes, they do at least provide a reasonable starting point for efforts to translate research principles into research goals. Therefore, if you would be willing to include suggestions for goals with your comments to me in revised principles, this would be most helpful.

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Documents relating to the development of the draft principles beginning with the Secretary's address before the Annual Meeting of the American Federation for Clinical Research in April through the National Conference will be published soon as the public record for this initiative to date. When ready, I will have this document sent to you.

Once again, I appreciate your interest and participation in this effort and look forward to your comments on the Conference Report. All comments must be received by February 1, 1979, and should be sent to: Kurt Habel, Chief, Program Planning Branch, Office of the Director, National Institutes of Health, Building 1, Room 205, Bethesda, Maryland 20014.

A handwritten signature in dark ink, appearing to read "DS Fredrickson", written over the typed name.

Donald S. Fredrickson, M.D.
Director

Enclosure

National Conference on Health Research Principles

October 3 and 4, 1978

Conference Report

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service National Institutes of Health

REPORT ON THE NATIONAL CONFERENCE
ON HEALTH RESEARCH PRINCIPLES

Department of Health, Education, and Welfare

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CONFERENCE CHAIRMAN'S

OVERVIEW

STATEMENT

CONFERENCE CHAIRMAN'S OVERVIEW STATEMENT

On October 3-4, 1978, DHEW Secretary Joseph A. Califano, Jr., convened a National Conference on Health Research Principles. At this Conference, five Panels--selected by the Secretary from nominees of all of the DHEW health agencies--heard testimony from many public witnesses concerning a draft set of principles developed by the agencies. At the close of the Conference, the Panels presented preliminary reports. These were edited by the Panel Chairmen, given to all Panel members for comment, and in some cases revised before submission as the conclusions of the Panels. The Conference staff then analyzed these final reports and prepared a revised set of draft principles based upon the Panels' recommendations. All of the above documents accompany this statement.

In accordance with the Secretary's policy of seeking public advice throughout this process, these documents are being presented now for evaluation by the Institute of Medicine and for public review. As this next phase of comment and revision proceeds, however, the DHEW agencies need not delay their consideration of the preliminary results of the process initiated by the Secretary last May. The present DHEW support and conduct of health research merit review in light of a number of the major conclusions of the Conference.

Health research in the United States has reached a stage of highly complex organization, fairly remarkable achievement, and heavy dependency upon government support--all in the space of a few decades. The promise of the enterprise still far exceeds its failings; and some perceptions of the latter are misconceptions of what science ought to be able to do and cannot do (at least now). Most of us number ourselves among the strong supporters of health research, but our reasons are highly diverse. Thus, any distillation of the essence of health research--the important principles upon which its public support and conduct should rest--must yield a diverse mixture. And such was the product of the Secretary's Conference. There was, however, one important control in the process not present in all similar deliberations. All participants had a common reference to consult, from which they could select certain qualities to be preserved or rejected, and from which they could also choose among initiatives to be encouraged; and finally they were allowed to add such principles as consensus seemed to permit. The resulting new fabric was to be rewoven on the warp of the original draft.

The revised principles are subjective and uneven. They are in need of further refinement, reordering, and transmutation to goals--the next phase in the process which the Secretary announced should be completed by next spring. The principles are, however, a more thoughtful and valuable beginning than many observers expected. They reflect angst of different kinds: that fundamental research not be sacrificed to expediency, that access to scientific help not be denied to any of the health missions, that an essential pluralism of health sciences not be stifled by monolithic creations, or that budget displacements not substitute for skillful management rearrangements designed to assure effective interaction and collective responsibility among the health agencies. Some of the Panels were reluctant to accept as a given the concept of austerity--the

requirement that any change be met through fiscal redeployment. However, this reluctance was accompanied by reasoned arguments on what alternative sources the commentator would use.

The Conference reports provide a litmus to test the status of certain concepts and definitions. The term "basic research" seems to have become too ambiguous to bear its important burdens. "Fundamental" is used in the reports and clearly implies research that is either laboratory- or clinic-based, aimed at mechanism, and not yet targeted toward specific, practical application in health care. The "Science Base" term now being tested by NIH in allocation definitions appears throughout the reports because it covers not only fundamental research but certain resources essential to that enterprise. Another area of much concern, health services research, was deliberately given a limiting definition of "scientific inquiry into problems associated with the actual organization, financing and delivery of health care services." Categorical clinical investigations, sometimes grouped with health services research, were advisedly aggregated under "applications" research, a category including multiple kinds of developmental research of importance to numerous agencies. The NIH is now using Applications Research as a second major allocations category. The third is Technology Transfer, a useful description for a research agency to define its activities closely complementing the service, health promotion, or regulatory missions of some sister agencies. The fourth category is Training or Manpower Development.

The SATT system --Science Base, Applications Research, Technology Transfer, and Training--could be adapted to analyze all DHEW health research or science activities. The importance of some such rationalization lies in recognition of strong recommendations that emerge from the Conference reports and revised principles calling for different ways to carry out the distribution of resources among these different categories. Thus it is suggested that the processes of selecting and financing "science base" and "applications" activities, whether within one agency such as NIH or across agencies, should rest on different principles, with needed funds perhaps coming from different purses.

The conferees offered concrete suggestions while reaffirming the essential Federal contribution to building the "science base." All five of the Panel reports contain suggestions for protecting and improving the knowledge-development capabilities that facilitate the health and survival of man and his world. Consideration of these proposals by both the Administration and the Congress is merited. They include potentially useful components of a multi-year budget strategy. The most frequent assertion of commentators was that DHEW support of the science base should be stabilized to the extent possible during the period covered by the multi-year strategy. As the Secretary noted in his address before the Annual Meeting of the American Federation for Clinical Research in April and reinforced at the Conference, the building of our current capacity of knowledge development represents a 25-year investment of the American people, and to jeopardize this investment so carefully assembled over the years would not be in the public interest.

The Panel reports also suggested budgetary and organizational changes. Some of these address areas where reorganization is under consideration with

DHEW. On the important issue of creating knowledge to meet the needs of regulators, the Panels, while not endorsing the concept of "mission-oriented fundamental research," did nevertheless support the need for effective capability in each agency to conduct research aimed at its immediate needs. The National Toxicology Program, recently formed to unite research and regulatory agencies along a common front, was not known to many of the conferees. In some aspects, it goes beyond any design proposed at the Conference.

A bold suggestion was made for establishment of a type of health research council at the Secretarial level to unite the agencies for collaborative efforts in applications and health services research. This is a level and degree of interaction greater than now exists. Two fairly radical suggestions were made in relation to this proposal. One was that health services research be conducted by an agency under the joint stewardship of such a council. Another was that a special (Secretarial) research fund be established from which searches for urgently needed new knowledge be funded. How such a fund might be administered, or how the Congress might view much of the proposal, is left to be considered. The structured interaction among all agencies that was proposed as a means to enhance the development and application of knowledge to all health missions deserves careful thought; many believe something like this is overdue. Creation of an appropriate mechanism for this purpose might be one of the minimum goals arising from this search for principles.

The conferees did express the view that if present strengths are to be maintained and enhanced, new organizational arrangements should occur around unmet health needs of mutual concern. This is the preferred alternative to broadening the research missions to embrace regulatory or care functions, or expanding the latter to include major research activity. Tomorrow's opportunities for improved health depend on research advances today, but such advances can only be impeded by a confusion of research and service. The ultimate goals of both are the same, but the short-term purposes, settings, skills, disciplines, and processes involved are not. More systematic ways of meeting regulation and health care needs could involve the resources of both the research agencies and the service and regulatory agencies, yet would not compromise the basic functions of either.

These highlights of the Panels' conclusions indicate that a useful process has been started. Whether the promise will be realized depends upon our continued efforts within DHEW, as they are also guided by the further contributions of many outside the Department who have compelling interests in the biomedical, behavioral, and social science components of health research.

Donald S. Fredrickson, M.D.
Director
National Institutes of Health

REVISED DRAFT
DHEW HEALTH RESEARCH PRINCIPLES

REVISED DRAFT DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH RESEARCH PRINCIPLES

The attached draft statement of DHEW Health Research Principles represents the combined suggestions of the following:

DHEW AGENCIES AND STAFF OFFICES

Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)
 Center for Disease Control (CDC)
 Food and Drug Administration (FDA)
 Health Care Financing Administration (HCFA)
 Health Resources Administration (HRA)
 Health Services Administration (HSA)
 National Center for Health Services Research (NCHSR)
 National Center for Health Statistics (NCHS)
 National Institutes of Health (NIH)
 Office of Assistant Secretary for Planning and Evaluation, Office of the Secretary (OASPE)
 Office of Health Policy, Research and Statistics, Office of the Assistant Secretary for Health (OHPRS)

HEALTH ORGANIZATIONS AND PROFESSIONAL SOCIETIES

- Over 1,000 health organizations and professional societies were asked to participate in the development of health research principles for the Department. Many organizations, societies and individuals responded by sending in suggestions both before and after the National Conference.

OTHER FEDERAL DEPARTMENTS AND AGENCIES

- Other Federal Departments and agencies were asked to contribute suggestions and advice on the principles. Many were received and have also been included in this process.

NATIONAL CONFERENCE PARTICIPANTS

- A large number of individuals, health organizations and professional societies who attended the National Conference provided testimony before one or more of the Conference Panels.

Their views are considered here, as well as providing significant input into the Conference Panel reports.

CONFERENCE PANEL REPORTS

- These reports were based upon the suggestions of the above organizations and individuals, as modified and extended by the deliberations of the Panels.

Background

The following statements concerning the scope of the Department of Health, Education, and Welfare (DHEW) health mission provide a context for the development of health research principles:

- In brief, the primary health missions of the DHEW may be characterized as Research, Prevention, Care, and Regulation. Total Department expenditures for these missions in FY 1977 were approximately \$38.0 billion.
- In FY 1977, the DHEW paid 23% of the Nation's health bill; approximately 7% of the total DHEW expenditures for health missions was for research and development activities.
- There are four major health research agencies in the DHEW (NIH, ADAMHA, NCHS, and NCHSR). However, other agencies (FDA, CDC, HSA, HRA, HCFA) carry out health research support of their primary missions. Total funding for health research and development in FY 1977 by all DHEW agencies engaged in health research was \$2.6 billion; support by the four major health research agencies was approximately \$2.5 billion (95% of the total).
- In FY 1977, NIH and ADAMHA provided 91% of all DHEW support for health research and development and 96% of the support for health research and development provided by the four major health research agencies. In 1977, NIH funding for health research was approximately \$2.2 billion; ADAMHA, \$153 million.

Introduction

In developing health research principles for the DHEW, it is important to recognize the following:

- Initially, the objective is to develop DHEW health research principles. These principles must be sufficiently specific to provide a context and framework for the subsequent development of a multi-year health research strategy.
- The principles must encompass the full spectrum of health research conducted and supported by the DHEW (including biomedical and

behaviorial research, health services research, epidemiologic and demographic research, research on disease control technologies, research in statistical and survey methodology, and health research communications), and must relate health research to the other health missions of the Department.

- The principles are intended to serve as a structure for the subsequent development of a strategy to guide the allocation of limited Federal research dollars and to influence the manner in which the DHEW will carry out its health research activities.

Health Research Principles

This statement of principles is organized around five major foci:

(1) fundamental research, (2) clinical applications and health services research, (3) health regulation and promotion, (4) research capability and (5) unifying concepts. The first three foci address segments of the health research continuum and together provide a structure to consider the health research activities of all Department health agencies and the knowledge base for all Department health missions; the fourth addresses resources for research (institutional, manpower, facilities and equipment) and the fifth serves as an integrating force to bridge and relate the others.

To deal adequately with the principles, the Panels found it necessary to define some terms. The revised principles should be viewed within the context of the following definitions:

- Fundamental Research - a search for new knowledge directed toward increasing our understanding of life, health and disease. The terms of reference are scientific inquiry into fundamental processes of biology and behavior. This science base includes both undifferentiated research tending to be isolated from a specific disease orientation, and clinically oriented research focusing more on specific disease processes.
- Clinical Application - the further development and assessment of knowledge for immediately practical purposes. Clinical trials, comprising the largest element in this category, are defined as research activities undertaken to assess the value and effect of prophylactic, diagnostic, or therapeutic agents, devices, regimens, procedures, etc., in human subjects. Other activities included under "clinical application" are research on the development of vaccines, other biologics, drugs, instruments, and devices. These several activities result in knowledge which may be immediately applicable to man and which may enhance the quality or duration of life.
- Health Services Research - scientific inquiry into problems associated with the actual organization, financing and delivery of health care services. Health services research has both applied and fundamental components, but is less categorical and more process-oriented than is research into clinical applications. Federally supported health services research includes both program specific and general health services research.

- Transfer - includes the application of clinical knowledge to clinical practice. To assure that appropriate and necessary health technologies are introduced into widespread clinical practice, there must be recognition that transfer follows, as a continuum, from the results of clinical applications and health services research. This does not imply that this process is always linear. Indeed, it rarely is. Rather, feedback from clinical practice contributes to establishing priorities for applied and basic research.

FUNDAMENTAL RESEARCH

This focus addresses the need for fundamental research (the search for knowledge about fundamental processes of biology and behavior), the creative process that governs this type of research activity, and the role of fundamental research in improving public health and providing the essential knowledge base upon which other Department health missions rely. This focus also encompasses the issue of stability of research support and the relationship of fundamental research to other activities in the health research continuum.

Principle--A national commitment to fundamental research is essential to meet the full range of public health expectations.

- The Federal investment in fundamental research must be maintained to develop the knowledge base essential to support the health research continuum that extends through applied research to the prevention, diagnosis, and treatment of disorders and diseases and to rehabilitation. This should be recognized as a long-term investment that provides the freedom for scientists to pursue diverse research topics that may not be immediately relevant to practical health problems.
- This national commitment must include long-term, stable support for fundamental research. This support is essential for the maintenance and strengthening of the scientific knowledge base related to all DHEW health missions.
- The development of new knowledge through fundamental research, and its application, has a significant impact in improving our ability to prevent disease and the effectiveness of treatment and rehabilitation.
- The decision to fund fundamental research in a given area should be based upon an assessment of related ongoing research and new scientific opportunity. The peer review system must be regarded as an efficient and essential instrument in the conduct of research grant programs.
- Investigator-initiated research proposals must continue to be emphasized in the conduct of fundamental research, and must be restored to their previous prominence as the primary mechanism in

the allocation of funds.

- Recognition must be given to a broadened concept of health factors and a research base developed to investigate them. This base should include studies in the behavioral sciences and population sciences such as epidemiology and biostatistics.
- The Directors of NIH and ADAMHA should conduct annual program reviews to update projections and review amounts needed in fundamental research, to identify new areas warranting support, to curtail inappropriate distribution among areas already being supported, to monitor the allocation of resources to fundamental research, and to review the allocation of resources among the various fields.

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

This focus addresses the development of the knowledge base to support the health care function, the need to acquire, validate and apply new knowledge, the characteristics of and requirements for applied, problem-oriented research, and the need to retain and strengthen the Department's pluralistic approach to the support of applied research.

Principle--To improve the quality of health care, prevent disease and contain health care costs, the health care system requires, in addition to new knowledge developed at the fundamental level, the support of applied, problem-oriented health research.

- The development of an adequate knowledge base for the fulfillment of health care missions must be supported. This includes strengthening fundamental research, as well as applied research approaches to the solution of health problems, in order to develop systematic ways to meet the needs of non-research health agencies for specific knowledge. This includes giving an appropriate priority for stable funding to certain research areas, such as epidemiology, biostatistics, toxicology and nutrition.
- The health research agencies must be responsible for assisting the health regulatory, care and policy-making agencies, whenever a formal request for assistance is made which clearly falls within the mission of the research agencies. Consideration should be given to the resources necessary to comply with such requests. The many applied health research needs which cannot be filled through such a system should be addressed by applied, mission-related research funded through the budgets of the health regulatory, care and policy-making agencies. Coordination and dissemination of the required knowledge should be provided through interagency committees responsible to the Office of the Secretary.
- The validation of preventive and therapeutic measures before their introduction into the health care system must be assured and

standards for their application in medical practice determined. This includes the validation of new regimens in terms of their efficacy, safety, and cost-effectiveness.

- After the introduction of preventive, therapeutic and diagnostic measures into actual use, monitoring programs should be employed to evaluate both their costs and benefits. This function should be part of a strengthened activity in health services research and technology assessment within the Office of the Assistant Secretary for Health. In addition, a fixed and adequate percentage of the budget of health care agencies should be devoted to these monitoring programs.
- The conduct of fundamental and applied research to improve methodologies for statistical, epidemiological, sociological and economic measurements in the health fields must be supported. This includes a long-term commitment to continuation and expansion of applied measurement research in statistical and survey methodology to provide improved statistics on morbidity and mortality, disease prevalence and incidence, disability prevention, behavior, enhancement of quality of life outcomes, the organization, delivery and financing of health care services, and new methods to facilitate epidemiologic analyses of large health data files. Funding for such methodologic research should occur at a reasonable level independent of support for specific health programs.
- A strategy must be adopted for funding health research which includes provision for specific program expansions for the support of clinical applications, clinical trials and health services research activities without diversions of funds from fundamental research. This includes the development and funding of multi-year, high-cost investigations and clinical trials as direct add-ons to specific agency programs where an adequate and available science base exists. If budgetary increases cannot be accomplished to provide such funds, then the health care dollar should be considered as a source. Priorities should be established for funding these activities, based on the state of the science base related to each effort, the feasibility of each effort, based on the state of the knowledge and available resources, the potential impact of the trial on research, health care, the burden of illness, and various ethical considerations. The public sector, academic centers and appropriate elements of the private sector should be an integral part of this process.
- The scientific merit of proposals for clinical investigations, clinical applications and health services research is a necessary condition for support. Each agency sponsoring such research should administer a peer review process to determine the scientific merit of each research proposal, and the reviewers should include nongovernment persons from appropriate disciplines.
- The systematic dissemination of health services research results to providers of health services requires more emphasis, so that advances in knowledge are applied by the health care system as

promptly and effectively as possible. However, care must be taken to avoid premature introduction of unproven new health technologies. Further research and evaluation are needed to determine the most efficient and effective methods of technology transfer.

- Consensus development approaches for providing information and technical transfer should be strengthened to assure the involvement of all constituencies relevant to the specific health technologies addressed.
- Priorities for health services research support must be defined, and the social value of anticipated findings should be a determining factor in this process. In defining priorities, the following should be considered:
 - State of the science base and the feasibility of each proposal, in terms of the state of knowledge and available resources;
 - Demand for the information likely to be generated by the study--the probability that it will be put to use--in terms of the potential impact on health care, the burden of illness, and various ethical issues.
 - Likelihood that the research will test assumptions on which current policies and delivery practices are based, provide the basis for developing new options for health services delivery, or provide the means for monitoring performance of the health care system;
 - Provision of flexibility for innovative proposals;
 - Participation in the process by those responsible for providing the research support, as well as those directly associated with the problems and needs;
- Planning and coordination of applied health research activities among DHEW agencies need to be strengthened, although the Department's present pluralistic approach to the support of clinical applications and health services research must be maintained.
- Planning and coordination can best be accomplished by establishment of a committee at the level of the Office of the Secretary, which includes representatives of all DHEW agencies involved in applied health research. The committee would serve generally to monitor the Department's commitment to provide an applied research capability, evaluate priorities and identify gaps and duplications of effort. Authority for program-specific research should remain within each agency. General health services, which is primarily the function of the National Center for Health Services Research, should be maintained as such, and the Center should become the operational arm of the committee. Coordination must also be

increased between HEW and private industry, particularly in the area of developmental research.

HEALTH REGULATION AND PROMOTION

This focus addresses the further development of the knowledge base necessary for regulatory decisions and preventive and control measures, the need to communicate effectively the nature and inherent constraints of the regulatory process, and the need to explore more structured and creative interactions between the health research agencies and the agencies responsible for health promotion and regulatory activities.

Principle--The knowledge base necessary to protect the public health through the establishment of preventive measures, the conduct of health education and promotion activities, and the formulation of regulations must be further developed.

- Progress in health regulation and promotion requires an increased commitment to health research, both basic and applied. The behavioral sciences are an integral part of this effort.
- Support of fundamental research should continue to be the responsibility of NIH. The NIEHS and NIOSH have a special role in adding to and exploiting basic knowledge to improve our understanding of environmental and occupational hazards. The support of applied research that is necessary to convert limited information into scientifically acceptable regulatory and control options should continue to be pluralistic.
- New approaches must be explored to assure that the knowledge needs of the regulatory agencies are clearly and systematically communicated to the health research agencies and that health research is responsive to these needs.
- The public should be informed about the nature of the regulatory process, its strengths, and limitations, including the constraints imposed upon it by the frequent need to make immediate decisions based on available knowledge.
- Research (most of it basic) should be supported to determine the most effective means of health promotion and disease prevention, the best ways of transmitting information to effect changes in behavior, and how specific measures can be most effectively directed to different populations. Programmatic approaches for health promotion research should stress the total range of interrelated health conditions.
- The public must be encouraged to improve health by adopting preventive measures and, when necessary, altering nutrition, environments, lifestyles, and behavior to reduce the risk of disease, disability, and premature death. Such measures are more beneficial and less costly in the long-run than pursuing curative

or rehabilitative approaches. More reliable data bases should be developed to help guide such decisions.

- Research is needed to provide broader and more accurate data bases and assessments of well-being and effective social function as well as more accurate measures of the burden of illness.
- In order to promote better health and to prevent illness, intensive and innovative cooperative efforts must be pursued by the government, health professionals, voluntary health organizations, and others in the private sector so that the public may be better informed and educated about the application of knowledge gained through research.
- An expanded effort to support large-scale epidemiologic studies should be initiated as an approach to health protection. Such studies should include the natural history of disorders and the identification and quantification of both risk and protective factors.
- The Secretary, DHEW, should be empowered to maintain an undesignated research fund to be allocated by an interagency coordinating committee with representation from NIH and the regulatory and service agencies for the purpose of dealing with urgent problems that arise unexpectedly in the health protection and health promotion areas.

RESEARCH CAPABILITY

This focus addresses the need to assure that the resources, both physical and human, necessary for the conduct of research are available.

Principle--Present research capabilities must be sustained and enhanced to assure future health gains.

- Human resources must be renewed and maintained:
 - It is essential to bring into the research community new investigators with new and innovative ideas and to provide them with support to capitalize on opportunities. Individual peer-reviewed project grants, institutional fellowships and some new and innovative highly targeted programs are some of the mechanisms through which this could be accomplished. This is necessary to train and maintain the next generation of investigators. Research careers must be kept competitive with other pursuits in order to attract and train outstanding individuals.
 - Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and medical careers. Support at both the pre- and postdoctoral levels are necessary to accomplish this.

- Recruitment of young researchers to areas of greatest national need and scientific promise must be encouraged. Mechanisms that may aid in doing this are individual research career development awards, individual and institutional fellowships, and new and young investigator and academic awards.
- Clinical research depends upon providing opportunities for promising clinically trained individuals with aptitude for research to develop into independent investigators as well as for Ph.D.'s to enter clinical and other research disciplines.
- It is essential to provide opportunities to individuals who have just obtained health professional or research degrees to embark on academic and/or Federal research careers.
- Investigators of proven productivity should be able to depend on stable research support during their demonstrably active careers and should be buffered against radical short-term changes in policy.
- Programs to encourage the research training and research grant support of minority investigators and institutions should be continued and expanded.
- Programs designed to enable capable young women to compete successfully for research support should be provided.
- Programs to support multidisciplinary, collaborative research approaches must be available.
- Programs need to be established and/or expanded in research areas currently undermanned, such as biostatistics, epidemiology, demography, sociology, environmental and occupational health.
- Major research activity at research and academic institutions such as health professional schools, graduate schools and Federal and National laboratories, such as the NIH intramural research program, must be fostered, and research support provided in a stable manner. Performance of research is inseparable from the learning process, enriching both directly and indirectly the quality of health care:
 - Investigators and institutions need some measure of stability and should be buffered against radical short-term changes in policy.
 - It is essential to provide an adequate level of long-term support to assure stability of training programs concerned with fundamental and clinical research in biomedical and behavioral disciplines.
- Physical resources must be renewed and maintained. This requires

giving attention to both equipment and facilities, since both are major determinants in the productivity of capable scientists.

- Resources should be conserved through sharing, methods developed to stimulate greater ingenuity in the design and construction of laboratories and buildings, and support for health science libraries and other biomedical communication resources continued and expanded.
- Grants for improvement of existing and construction of new animal facilities must be continued and expanded, as well as support for breeding and base-line characterization of needed research animals. The potential for preservation of stocks of organisms in the dormant state should be explored, as should reliable methods for frozen maintenance centers and distribution of stocks when called for.
- A continuous assessment of ongoing needs and resources should be pursued. Additional studies of the future of junior faculty positions are needed, and the employment model used in estimating needs for the number of trained individuals and disciplines should be expanded into a more complete job market. Data to evaluate and monitor the condition of existing facilities and equipment are needed.

UNIFYING CONCEPTS

This focus deals with concepts that provide the basis for consideration of the philosophic base for public funding of health research and the interactions among the different parts of the research continuum necessary to move from the development of new knowledge to the application of research findings. Considerations include the need: to reaffirm the Federal support of health research; to fulfill public expectations regarding a return on the public's investment in health research; to communicate effectively the nature of the scientific process, its limitations and benefits; to develop bridges between fundamental and applied research; and to explore new interactions and processes.

- The Federal Government should support health research, and the rationale for such support should be clearly presented to the public which makes such support possible.
- There should be long-term stability in the funding of health research, but within this stability of funding there should be sufficient flexibility to allow for a rapid response to promising new research opportunities.
- Fundamental research should be defined broadly and the need for a science base (or basic research) should be reaffirmed.

- The funding and training of young investigators are essential to the future of health research.
- The decision-making process in the formulation of health research policy should be both open and accountable.
- Health research policies should be formulated in the light of a gradually evolving set of ethical and legal standards for the conduct of such research.
- Efforts to involve previously underrepresented groups in health research should be continued.
- DHEW agencies can perform an important matchmaking function by identifying mutually relevant and reinforcing research efforts.
- The criteria for setting health research priorities among various fields and approaches should not be rigidly defined, but should consider a variety of factors ranging from research opportunity to social need.

ANALYSIS OF DRAFT DHEW
HEALTH RESEARCH PRINCIPLES
PRESENTED AT THE NATIONAL CONFERENCE

FUNDAMENTAL RESEARCH

- Principle -- A national commitment to fundamental research is essential to meet the full range of public health expectations.

(The Fundamental Research Panel report strongly endorsed this principle, as did public testimony provided by registered witnesses and public suggestions received from professional societies and health organizations. The Clinical Applications and Health Services Research Panel report emphasizes that funds should not be diverted from fundamental research to support clinical applications, applied health services research, or transfer activities. The Health Regulation and Promotion Panel report states that progress in health protection and promotion required an increased commitment in Federal funds for both basic and applied research. The Unifying Concepts Panel report stated that the need for a science base (basic research) should be reaffirmed.)

- This national commitment must include long-term, stable support for fundamental research. This support is essential for the maintenance and strengthening of the scientific knowledge base related to all DHEW health missions.

(The Panel report supported this concept and stated that the assurance of stable support for productive investigators of excellence is a matter of national concern and that fundamental research must be steadily supported in order to attain the goal of promoting the well-being of man. Several suggestions in this Panel report to provide stability are: limited delegation of Federal resources to institutions, such as in the Biomedical Research Support Grant program, preservation and strengthening of the relatively undifferentiated elements of the national system through the mechanism of general research support, and the reversal of the trend to short-term funding of regular individual research projects led by investigators of proven competence. The Research Capability Panel report endorsed this concept as did the Unifying Concepts Panel report. The latter suggested that there should be long-term stability in the funding of health research, but within this stability there should be sufficient flexibility to allow for a rapid response to promising new research opportunities. Testimony provided by registered witnesses, as well as suggestions received from health organizations and professional societies also supported this concept.)

- A reasonable level of Federal investment in fundamental research must be maintained to develop the knowledge base essential to support the health research continuum that extends through applied research to the prevention, diagnosis, and treatment of diseases and disorders and rehabilitation. This should be recognized as a long-term investment that provides the freedom for scientists to pursue diverse research topics that may not be immediately relevant to practical health problems.

(The Panel report was in agreement with this concept and stated that fundamental research should be stabilized in constant dollars with appropriate increments for growth. A minority view was expressed that the

costs associated with this stabilization might be subject to funding derived from a percentage of the gross proceeds of the health care delivery system. The weight of both the testimony provided by registered witnesses and suggestions submitted by health organizations and professional societies was supportive of this concept.)

- There should always be adequate mission outlets to bring basic research results to fruit and always enough basic research support to ensure that missions do not outrun their research base.

(The Panel report does not address this statement directly, nor did the weight of testimony provided by registered witnesses or suggestions from the professional societies and health organizations. The other Panel reports did not directly address this concept either. However, the Fundamental Research Panel report, corroborated by public testimony, did emphasize the need for stable support for fundamental research at a reasonable level, and also contains the view that resources for fundamental research should not be diverted to short-term goals. In addition, the Clinical Applications and Health Services Research Panel report emphasizes that funding should not be diverted from fundamental research to provide resources for the needs of clinical applications, applied health services research, or transfer activities.)

- The development of new knowledge through fundamental research and its application, although not a total solution, can have a significant impact on reducing health costs by improving our ability to prevent disease and the effectiveness of treatment and rehabilitation.

(The Panel report does not address this concept directly; however, suggestions from health organizations and professional societies support the view that fundamental research is the most cost-effective approach to attain health goals in the long run. In the few instances that this concept was touched upon by the registered witnesses, the testimony was supportive.)

- The decision to fund research in a given area should be based upon an assessment of ongoing research and new scientific opportunity and evaluation for scientific excellence that must remain the critical criteria for research support.)

(The Panel report endorsed this concept and suggested that annual program reviews of fundamental research conducted by agency heads be based upon an assessment of ongoing research and new scientific opportunities as well as the availability of the required scientific talent and the perceived social need. The Research Capability Panel report states that only research of the highest quality is worth doing and should continue to be the criterion for support. Public suggestions received from professional societies and health organizations strongly endorsed this concept, as did the weight of public testimony presented at the Conference.)

- Investigator-initiated research must be fostered. Investigator-initiated research underpins the health research network, provides a large measure of stability to the system, and

plays a critical force in the development and expansion of knowledge.

(The Panel report states that the individual research grant is the most effective mechanism for the support of creative, fundamental research. The report recommends that investigator-initiated research proposals must be restored to their earlier position as the primary mechanism in the allocation of funds. The weight of public testimony by registered witnesses was supportive of this concept, as were the suggestions from health organizations and professional societies.)

- Basic research is surrounded by, and must relate closely to, an area of applications research.

(This concept was rejected by the Panel report and the public testimony by registered witnesses. The report states that the Panel took particular issue with this concept, and that this same concept evoked the most comment from the registered witnesses. Comments ranged from an expression of the belief that the strength of future breakthroughs in disease prevention and control lies in the support of basic research, that one cannot always know or predict the clinical relevance of basic research, that most basic research should not be targeted, and that "targeted basic research" should only be used sparingly, that basic research cannot be made to rest on any constraint of relevance, and that it is a confusion of priorities to limit fundamental research support to what seems to be particularly relevant. The Panel report defines fundamental research as a search for knowledge directed towards increasing our basic understanding of life, health and disease. The Unifying Concepts Panel report addressed the question of the "health research continuum," and although agreement was not reached on what the continuum is, the Panel report does recommend that fundamental research be construed broadly, without reference to any particular type or level of aggregation.)

- Recognition must be given to a broadened concept of health factors and a research base developed to investigate them. This base should include studies in the behavioral sciences and population sciences such as epidemiology and biostatistics.

(The Panel report did not address this concept; however, testimony by registered witnesses, as well as suggestions from professional societies and health organizations was supportive. Both the Clinical Applications and Health Services Research Panel report, and the Health Regulation and Promotion Panel report, recognized the need for additional studies in the area of biostatistics and epidemiology.)

ADDITIONAL SUGGESTIONS IN THE FUNDAMENTAL RESEARCH PANEL REPORT

- The allocation of support to fundamental research is best maintained by continuation of the present pluralistic system, that is, one in which most allocations are determined by the immediate and long-term relevance of such research to categorical missions, with an additional source of allocations to cover areas whose relevance to particular categorical missions may be less immediately apparent.

- There should be annual reviews of fundamental research to update projections, identify new areas warranting support, curtail inappropriate distribution among areas already being supported, and review amounts needed; and the Directors of NIH and ADAMHA should monitor the allocation of resources within Institutes to ensure the stability of this long-term commitment. The distribution of support among the various fields or areas of fundamental research is the responsibility of the Directors of NIH and ADAMHA.
- The peer review system must be regarded as an efficient and essential instrument in the conduct of research grant programs, the initial review groups should no longer be classified as public advisory groups, all research grant applications should be processed through regular study sections, which should be strengthened, and special study sections should be convened where necessary for review of applications for core facilities.

ADDITIONAL SUGGESTIONS IN THE FUNDAMENTAL RESEARCH PANEL REPORT
FOR CONSIDERATION UNDER OTHER CONFERENCE FOCI

- A renewed commitment to research training of M.D.'s and Ph.D.'s is required. This commitment should provide a stable environment for the development of young scientists. Individual training awards of up to five years, institutional research training grants, the Medical Scientist Training Program, and career development awards are essential to meeting this commitment. (This will be considered under the Research Capability focus.)

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

- Principle -- To improve the quality of health care, prevent disease and contain health care costs, the health care system requires, in addition to new knowledge developed at the fundamental level, the support of applied, problem-oriented health research.

(This principle was endorsed by the Panel report and was consistently supported by the public witnesses and the written public statements.)

- The development of an adequate knowledge base for the fulfillment of health care missions must be supported. This includes strengthening all approaches to the solution of health problems as well as developing systematic ways to meet the needs of non-research health agencies for specific knowledge.

(The need for developing an adequate knowledge base for the Department's health care missions was recognized by the Panel report, and was noted by many of the public witnesses and persons who submitted written comments. The Panel report stated that fundamental research as well as the application of fundamental research to the solution of clinical problems is and should continue to be addressed. The Panel report also emphasized that certain applied research areas or disciplines such as epidemiology, biostatistics, toxicology and nutrition must have an appropriate priority for stable funding and that in these areas there is a core of research which is multidisciplinary in nature and whose findings have general applicability to a number of problems. The Health Regulation and Promotion Panel report reinforces this view. In addition, the Panel report expressed the view that NIH and ADAMHA have a responsibility to assist the regulatory and policy-making agencies when called upon to do so, but only when the request falls clearly within the mission of these agencies. The report recognizes that additional resources necessary to assist must be considered and that Congress and the Executive Branch should recognize the needs of the regulatory and service agencies for applied, mission-related research through provision of funding within agency budgets. The report suggests that the coordination and dissemination of the required knowledge should be provided through interagency committees responsible to the Office of the Secretary, DHEW. In addition, both the Health Regulation and Promotion and the Unifying Concepts Panel report recognize that greater opportunity exists for research and non-research agencies to interact in meeting the latter's needs.)

- The validation of preventive and therapeutic measures before their introduction into the health care system must be assured and standards for their application in medical practice determined. This includes the validation of new regimens in terms of their usefulness, efficacy, safety, cost-effectiveness and potential superiority over those already in use.

(The Panel report endorsed this concept and extended it by recommending

that after the introduction of preventive, therapeutic, and diagnostic measures into the health care system, monitoring programs should be established to provide the data base for evaluative measures of both costs and benefits of the use of new methods in actual practice. The report recommends that this latter effort should be the function of a strengthened activity in health services research and technology assessment within the Office of the Assistant Secretary for Health. The Health Regulation and Promotion Panel report recommends that a fixed and adequate percentage of the budget of health care agencies should be set aside for the purpose of acquiring a reliable data base to permit the determination of the efficacy of services provided. The written public comments supported the principle in a similar manner, as did the witnesses, although the latter group emphasized cost-effectiveness more than other factors.)

- The conduct of applied research to improve methodologies in the field of health and demographic statistics must be supported. This includes continuation and expansion of basic measurement research in statistical and survey methodology to provide improved statistics on mortality, disease prevalence and incidence, health practices and new methods to facilitate epidemiologic analyses of large health data files.

(The Panel report concurred with this statement and recommended that fundamental research for statistical, epidemiological, sociological and economic methodology needs to be supported to provide improved measures and quality statistics on disease prevalence and incidence, morbidity and mortality, disability prevention, behavior, enhancement of quality of life outcomes, and the organization, delivery, and financing of health care services. The Panel report suggested the need for a long-term commitment to the improvement of these methodologies, and recommended that methodologic research be funded at a reasonable level independent of support for specific health programs. Those public witnesses addressing this concept generally concurred with it. The Health Regulation and Promotion Panel report also suggested that more research in these areas is required.)

- A strategy must be adopted for funding health research that includes provision for specific program expansions for the support of clinical applications, clinical trials and health services research activities. This includes the development and funding of multi-year, high-cost investigations and clinical trials as direct add-ons to specific agency programs where an adequate and available science base exists. The public sector, academic centers and appropriate elements of the private sector should be an integral part of this process.

(Specific program expansions for clinical applications and health services research activities were supported by the Panel report and many of the other Conference participants. The Panel report emphasized that such increases should not be accomplished by diverting funds from fundamental research, and suggested that the health care dollar should be considered as a source of funds, if budgetary increases could not be considered. Criteria for establishing priorities for these activities

which were recommended in the Panel report include the state of the science base related to the effort, the feasibility of the effort based on the state of the knowledge and available resources, the potential impact of the trial on research, health care, the burden of illness, and various ethical considerations.)

- The scientific merit of health services research is a necessary condition for support.

(This concept was extended by the Panel report to include not only health services research but also clinical investigations and clinical applications research. The Panel report further stated that the method of determining scientific merit should be through a peer review process administered by each agency which sponsors these research activities to assure scientific merit, and that the peers should include non-government persons from appropriate disciplines. None of the witnesses or written public comments addressed this principle directly, but the use of a peer review process for evaluation of health care research activities was recommended by a number of registered witnesses.)

- The systematic dissemination of research results and related activities for technical consensus development must occur so that advances in knowledge are applied to the health care system as promptly and effectively as possible.

(The Panel report restated this concept in two parts as follows: "The dissemination of health services research results to providers of health services requires more emphasis" and "technical consensus development approaches for providing information and technical transfer should be strengthened to assure the involvement of all constituencies relevant to the specific health technologies addressed. The report also noted the importance of avoiding premature introduction of new health technologies. This principle was supported widely throughout the testimony of the public witnesses and the written public comments. Related recurring themes in the public comments were a recommendation that further research and evaluation are needed to determine the most efficient and effective methods of technology transfer, and a recommendation that technology transfer be a shared responsibility of Federal agencies, the health research community, private organizations and industry.)

- Priorities for health services research support must be defined, and the social value of anticipated findings should be a determining factor in this process. In defining priorities, the following should be considered:
 - Participation in the process by those responsible for providing the research support, as well as those directly associated with the problems and needs;
 - Provision of flexibility for innovative proposals;
 - Likelihood that the research will test assumptions on which current policies and delivery practices are based, provide the

basis for developing new options for health services delivery or provide the means for monitoring performance of the health care system;

- The demand for the information likely to be generated by the study;
- The probability that the findings will be put to use.

(The Panel report suggested that the following criteria be considered when establishing health services research priorities: The state of the science base, the feasibility of each proposal in terms of the state of knowledge and available resources, the potential impact of each research activity on health care, on the burden of illness, and the relationship of various ethical considerations. The responses of the public witnesses and persons submitting written comments were similar to those of the Panel report, and added that alternative funding sources within the public and private sectors should be considered. The testimony of the public witnesses also repeatedly stated the need for health services research to test the assumptions on which current policies and practices are based.)

- DHEW's present pluralistic approach to the support of clinical applications and health services research must be maintained; planning and coordination among DHEW agencies need to be strengthened and new funding arrangements explored.

(This principle was supported by the Panel report, public witnesses and persons submitting written comments. However, the Panel report expanded this concept to recommend the establishment of a committee at the level of the Office of the Secretary, to include representatives of all agencies involved in applied research. The committee would serve to monitor and guide the Department's applied health research efforts, by evaluating priorities and by identifying gaps and duplications of effort. The report further recommends that authority for program-specific health services research should be within each agency and that support for this research should be an integral part of its operating budget, while general health services research, which is primarily the function of the National Center for Health Services Research, should be maintained and the Center should become the primary operational arm of the committee.

Another area which the Panel report cited as warranting increased coordination was the relationship between DHEW and private industry. Private industry has traditionally held the largest responsibility for developmental research - the translation of basic observations into preventive, diagnostic and therapeutic products. Increased interaction with private industry was recommended to insure optimal utilization of new information.)

ADDITIONAL SUGGESTIONS BY THE CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH PANEL FOR CONSIDERATION UNDER OTHER
CONFERENCE FOCI

- Funding should not be diverted from fundamental research to provide resources for the needs of clinical applications, applied health services research, or transfer activities. (This will be considered under the Fundamental Research focus.)
- The need for improved measurement methodologies in health statistics, epidemiology, sociology and economics requires a long-term commitment, including the support of training of sufficient numbers of qualified researchers, such as biostatisticians, epidemiologists, demographers, sociologists, health economists, and health systems analyst. (This will be considered under the Research Capability focus.)

HEALTH REGULATION AND PROMOTION

- Principle -- The knowledge base necessary to protect the public health through the establishment of preventive measures, the conduct of health education and promotion activities, and the formulation of regulations must be further developed.

(The Panel report endorsed this principle, stating that "progress in health regulation and promotion requires an increased commitment of Federal funds for health research, both basic and applied" The Panel expressed the view that the support of the behavioral sciences is an integral part of this effort. The weight of testimony provided by public witnesses also supported this principle.)

- Between fundamental and applications research, there is mission-oriented fundamental research with a class of studies intermediate in character. This class of studies serves regulatory needs and has not been adequately addressed. The regulatory agencies of DHEW should be given the leading role in the support, planning and conduct of this research.

(This statement was not endorsed in the Panel report. The Panel report did not identify a type of research described as "mission-oriented fundamental research" between fundamental and applied research. Rather, the Panel report addressed both fundamental and applied research and emphasized that the knowledge base for regulatory action requires a variety of information sources ranging from fundamental research through short-term highly applied research. Neither the weight of public testimony by registered witnesses nor suggestions received by health organizations recognized the concept of mission-oriented fundamental research. However, both the Panel report and the public witnesses recognized the need for more studies in support of the regulatory function that could and should be undertaken within the context of the basic-applied research spectrum. The Panel report states that NIH should continue to be the major source of basic biomedical research and that the National Institute of Environmental Health Sciences and National Institute of Occupational Safety and Health have a special role in exploiting the basic knowledge resource for the purpose of improving our understanding of environmental and occupational hazards. There was no clear position stated as to whether regulatory or nonregulatory agencies should carry primary responsibility for short-range applied research necessary to convert limited information into scientifically acceptable regulatory and control options. The Panel report also expressed the view that basic research is not best carried within a control agency. In addition, the Fundamental Research Panel report did not endorse the concept that basic research must relate closely to an area of applications research. The Unifying Concepts Panel addressed the question of the health research continuum, and although agreement was not reached on a set of descriptors, the Panel report does recommend that fundamental research be construed broadly, without reference to any particular type or level of aggregation.)

- Intensive and innovative cooperative efforts must be pursued by the

government, health professionals, voluntary health organizations and others in the private sector so that the public may be better informed and educated about the application of knowledge gained through research in order to promote better health and to prevent illness.

(The Panel report did not directly address this statement; however, the weight of public testimony by registered witnesses and the public suggestions from professional societies and health organizations was supportive.)

- The public must be encouraged to improve health by adopting preventive measures and, when necessary, altering nutrition, environments, life styles and behavior to reduce the risk of disease, disability and premature death. Such measures are more beneficial and less costly in the long run than pursuing curative or rehabilitative approaches.

(The Panel report supported this statement and recommended that more reliable data bases be established to help guide decisions about altering environments, life style, nutrition and behavior. The Panel emphasized that the major rationale for such measures should be an increase in well-being, not cost savings. Testimony provided by public witnesses at the Conference, as well as suggestions received from health organizations and professional societies, was supportive of this concept.)

- Research should be supported to determine the most effective methods of providing preventive services and health education aimed at prevention, and a better balance should be sought between research focused on prevention as opposed to research directed at therapies.

(The Panel report recommended a higher priority for research (much of it basic) to determine the most effective means of health promotion and disease prevention, the best ways of transmitting information to lead to changes in behavior, and the circumstances under which specific measures can be most effectively directed in different populations. The Panel report also suggested that research for health promotion must include programmatic approaches that stress the total range of interrelated health conditions rather than categorical illness alone. The Panel report stated that research directed at prevention and research directed at treatment is not tantamount to basic vs. applied research, for in many instances only basic research can yield the knowledge necessary for prevention. Both the testimony of the public witnesses and the suggestions of health organizations were supportive of this statement.)

- The public should be informed about the nature of the regulatory process, its strengths and limitations, including the constraints imposed upon it by the frequent need to make immediate decisions based on current knowledge.

(Neither the Panel report nor the public testimony provided by registered witnesses addressed this statement.)

- Support of applied research to serve regulatory needs must be provided, and this research should continue to be conducted primarily by the regulatory agencies.

(The Panel report recognized the need for an increased commitment for both basic and applied research to support the regulatory function, including research on the effectiveness of health services, on the means of monitoring the health care system, and on establishing standards for health care. The Panel report expressed the view that the behavioral sciences must be an integral part of this effort. The report states that NIH should continue to be the major source of basic biomedical research and that, in addition, the National Institute of Environmental Health Sciences and the National Institute of Occupational Safety and Health have a special role for adding to and exploiting the basic knowledge resource for the purpose of improving our understanding of environmental and occupational hazards. The report also states that research resources should be responsive to the regulatory agencies for the transitional and short-range applied research necessary to convert limited information into scientifically acceptable regulatory and control options. There was no clear position stated as to whether the regulatory or nonregulatory agencies should carry primary responsibility for this type of short-range applied research, with arguments on both sides during Panel discussion and testimony from witnesses. The Panel report stated that basic research is not best carried out within a control agency.)

- New approaches must be explored to assure that the knowledge needs of the regulatory agencies are clearly systematically communicated to the health research agencies and that health research is responsive to these needs.

(The Panel report supports the latter half of this statement, and the public testimony received from public witnesses was supportive of this concept.)

ADDITIONAL SUGGESTIONS IN THE HEALTH REGULATION AND PROMOTION PANEL REPORT

- Research is needed to develop and provide broader and more accurate descriptions of well-being and social function as well as more accurate assessment of the burden of illness than is provided by the conventional measures of morbidity and mortality. Such methodologies are essential if we are to assess accurately the effectiveness of health protection and promotion activities.
- An expanded effort to support large-scale epidemiologic studies should be undertaken. This approach to health protection is vastly underutilized and should include studies on the natural history of disorders and the identification and quantification of both risk factors and protective factors.
- The Secretary of HEW should be empowered to maintain an undesignated research fund to be allocated by an interagency coordinating committee with representation from NIH and the regulatory and service agencies for

the purpose of dealing with urgent problems that arise unexpectedly in the health protection and health promotion area.

ADDITIONAL SUGGESTIONS IN THE HEALTH REGULATION AND PROMOTION
REPORT FOR CONSIDERATION UNDER OTHER CONFERENCE FOCI

- A fixed and adequate percentage of the budget of health care agencies should be set aside for the purpose of acquiring a reliable data base which will permit determination of the efficacy of the services provided. (This will be considered under the Clinical Applications and Health Services Research focus.)
- There should be greater support for institutional and project research within universities for the areas of biostatistics, epidemiology, behavioral sciences, environmental health and occupational health. (This will be considered under the Fundamental Research and Clinical Applications and Health Services Research foci.)
- There must be assured funding for the education of investigators in the above fields and for potential users of research information, and this funding should be supplied in a stable manner. (This will be considered under the Research Capability focus.)
- Joint efforts in the health research area between the Federal Government and voluntary health agencies, philanthropic foundations, State and local governments and industry should be explored. (This will be considered under the Unifying Concepts focus.)

RESEARCH CAPABILITY

- Principle -- Present research capabilities must be sustained and enhanced to assure future health gains.

(This principle was endorsed in the Research Capability Panel report and supported by the majority of registered witnesses who testified before the Panel.)

- Human resources must be renewed and maintained:

- It is essential to bring into the research community new investigators with new and innovative ideas and to provide them with support to capitalize on opportunities. This is necessary to train and maintain the next generation of investigators. Research careers must be kept competitive with other pursuits in order to attract and train outstanding individuals.

(The Research Capability Panel report supported this statement and suggested that support for new investigators should be provided in the form of individual peer-reviewed grants. Training grants and some highly targeted programs were mentioned in the Panel report as helpful. The freedom of investigators to develop their own research approach and to pursue leads in research was expressed. This statement was supported by those individuals providing testimony at the Conference, and is also reflected in the public suggestions received. The Panel also agreed that opportunities for careers in research must be kept competitive with alternative roles in practice, industry and administration. The Fundamental Research Panel report and the Unifying Concepts Panel report both endorsed this concept also, and the Fundamental Research Panel report suggested institutionally based training programs as a mechanism for providing a stable environment within which to develop young scientists.)

- Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and medical careers.

(The Panel report and individuals providing testimony agreed with this statement and suggested that there should be support for education and research training at both the pre- and postdoctoral levels in order to accomplish this. The statement was also supported widely through written public suggestions and by other Federal agencies.)

- Recruitment of young researchers to areas of greatest national need and scientific promise must be encouraged.

(This statement was endorsed by both the Panel report and the public witnesses. The Panel report suggested that mechanisms

that may aid the changing of plans rapidly as new opportunities develop are individual research career development awards, individual and institutional fellowships, and new and young investigator and academic awards.)

- Attention should be given to providing opportunities for promising clinically trained individuals with demonstrated aptitude for research to develop into independent investigators, as well as for Ph.D's to enter clinical and other research disciplines.

(This statement was supported by the Panel report, and suggestions received from the public agreed with the concept stated here.)

- It is essential to provide opportunities for persons who have just obtained health professional or research degrees to embark on academic and/or Federal research careers.

(The Panel report endorsed this statement without additional suggestion.)

- Programs aimed at the continuing education of health care practitioners must be encouraged so that new techniques, diagnostic tools, treatments and preventive measures which are the fruits of research can be passed on to the public through better medical care.

(The Panel agreed that this concept was an important one, but in their report stated that this concept did not fit their understanding of health research. The Panel felt that this concept was more properly addressed by those agencies responsible for health care.)

- Programs to support multi-disciplinary, collaborative research approaches must be available.

(The Panel report endorsed this statement and indicated some of these programs should be in clinical environments. This statement was also widely supported by public suggestions, comments from other Federal agencies, and public witnesses providing testimony at the Conference.)

- Major research activity at research and academic institutions, such as health professional schools, graduate schools and Federal and National laboratories, must be fostered, and research support provided in a stable manner. Performance of research is inseparable from the learning process, enriching both directly and indirectly the quality of health care:

(The Panel report endorsed this statement and emphasized the fact that Federal health objectives depend critically upon the health and vitality of the institution in which research is performed. They pointed out the need for a significant, reliable institutional

support program for sponsors of extramural research and the need for, as a priority of the first magnitude, the support of the NIH intramural program. Public witnesses testifying at the Conference supported this statement, as did organizations submitting public suggestions.)

- Investigators and institutions need some measure of stability and should be buffered against radical short-term changes in policy.

(The Panel report agreed with this concept and noted that in considering institutional support programs, flexibility is essential for research, especially to facilitate the launching of young investigators. Public suggestions received and testimony given also supported this concept. Both the Fundamental Research Panel report and the Unifying Concepts report endorsed this concept.)

- It is essential to provide an adequate level of long-term support to assure stability of training programs concerned with fundamental and clinical research in biomedical and behavioral disciplines.

(The Panel report endorsed this concept and indirectly concurred in the approach of determining the level of institutional support in terms of the magnitude of research conducted at research and academic institutions. The Panel also suggested that funding be provided for longer periods of time to provide stability. This concept was also endorsed by the public witnesses providing testimony at the Conference. The Fundamental Research Panel report and the Unifying Concepts Panel report endorsed this concept. Both the Clinical Applications and Health Services Research Panel report and the Health Regulation and Promotion Panel report endorsed this concept for undermanned areas identified in their reports--epidemiology, biostatistics, environmental and occupational health, etc.)

- Physical resources must be reviewed and maintained.

(The Panel report concurred in this statement and suggested the following: Promulgating a realistic national policy designed to assure the adequacy of physical facilities and equipment, the development of data on important characteristics of existing facilities, monitoring the adequacy of existing facilities, the sharing of existing resources, greater flexibility in the design and construction of facilities, the development of a realistic means of permitting a depreciation allowance, and the continued support and expansion of health science libraries and other biomedical communication resources. Support for this concept was also provided by public witnesses testifying at the Conference, as well as those submitting public suggestions from professional societies, health organizations and other Federal agencies.)

- A continuous assessment of ongoing needs and resources should be pursued.

(The Panel report concurred with this statement and felt that the reports of the National Academy of Science should receive appropriate attention, that additional studies of the future availability of senior faculty positions are needed, that the employment model used in estimating needs for the number of trained individuals - disciplines for biomedical and behavioral investigators requires expansion into a more complete job market, and that data to evaluate the condition of existing facilities and equipment is needed.)

ADDITIONAL SUGGESTIONS IN THE RESEARCH CAPABILITY PANEL REPORT

- Human Resources

- Investigators of proven productivity should be able to depend on stable research support during their demonstrably active careers.
- Programs to encourage the research training and research grant support of minority investigators and minority institutions should be continued and expanded.
- Programs designed to enable capable young women to compete successfully for research support should be carefully designed.

- Animal Resources

- Grants for improvement and new construction of animal facilities, to bring them into compliance with Federal guidelines and legal standards, must be continued and expanded.
- Support for breeding and baseline characterization of needed research animals must be provided, and the potentiality for preservation of stocks of organisms in the dormant state should be explored. Reliable methods for frozen maintenance centers should be developed, and cooperation among agencies for maintenance of needed stock promoted.

ADDITIONAL SUGGESTIONS IN THE RESEARCH CAPABILITY PANEL REPORT FOR CONSIDERATION UNDER OTHER CONFERENCE FOCI

- Research involving human and animal subjects should be conducted in accordance with the highest ethical standards, while allowing the continuing pursuit of essential research. (This will be considered under the Unifying Concepts focus).
- Better understanding is needed to delineate those ethical issues posed by studies of different population groups, as for example, research

involving children, the mentally disabled, prisoners, and groups with different value systems. (This will be considered under the Unifying Concepts focus.)

- New or changed therapeutic modalities should be introduced into general use in ways which provide assessment of their effectiveness. (This will be considered under the Clinical Applications and Health Services Research focus.)
- It is recommended that a declaration of the national policy and national objectives of the Federal role in health research be embodied in legislation. This legislation should authorize the overall research level, including necessary training, equipment, facilities and other support resources, for the five-year period--including subauthorizations. These subauthorizations for individual Institutes and other major health research programs should be expressed in current dollars in such a way as to avoid erosion of the research plan by inflation and should be continued uninterrupted should there be a delay in extending the legislation at the end of the five-year period. (This will be considered under the Unifying Concepts focus.)
- Only research of the highest quality is worth doing. High quality has been the key to past successes and will inevitably be essential for future advances. High quality has been achieved through the use of review panels of outside experts. The continued success of the health research effort depends on maintenance of the peer review system and its extension in other areas where applicable. (This will be considered under the Fundamental Research focus.)
- Health science planning sessions should be conducted openly. However, there is a real need to conduct certain scientific reviews to insure confidentiality and avoid inadvertent or premature disclosure of potentially patentable ideas whose eventual development could have impressive national benefits. Furthermore, unless scientific review deliberations can be conducted in an atmosphere which fosters the most candid and searching examination of proposals, the public interest is ill served. (This will be considered under the Unifying Concepts focus.)
- To assure effectiveness, productivity and objectivity of the health research assigned to the National Institutes of Health, it is proposed that the NIH be assigned only research and research related responsibility. This might best be expressed as establishing boundaries for NIH which exclude three activities:

Regulation
Promotion
Assumption of long-term care

It is considered that activities in these three areas would be incompatible with the primary research responsibility of NIH, would have potential for impairing credibility as to objectivity of research performed, and would violate the major premises of the scientific method. (This will be considered under the Unifying Concepts focus.)

UNIFYING CONCEPTS

- Premise - The social context for the conduct of health research has changed to one of greater public accountability. A reaffirmation of the public commitment to health research and a restatement of the rationale for Federal support are needed. This reaffirmation must address the responsibilities and expectations of both the health enterprise and the public that underwrites it.

(The draft principles presented at the National Conference under this premise suggested that the public should expect a number of returns on its investment in health research and, to meet the public's expectations, the Federal agencies supporting and conducting health research should engage in a number of activities. The Panel report does not address the draft principles specifically, but rather sets out general areas for additional consideration. The Panel report agrees that the Federal Government should support health research but that the rationale for such support should be clearly presented to the public. The report suggests several rationales for such support - an historical one, an esthetic one, and one leading to more effective and economical health care - but indicates that the strongest argument is the results of health research. The report acknowledges that science base or fundamental research activities are the most difficult to justify to the public. Increased efforts to present health research to the public were supported by the Panel. Testimony by witnesses endorsed this view also.

The Panel also considered the role of the public in the health research decision-making processes, noting the increased participation of the public over the years. The Panel report supported the view that decision-making in the formulation of health research policy should be both open and accountable, but that the scientific merit of scientific proposals should be evaluated by scientists expert in the area of the proposed research. The Research Capability Panel report also supported this view, noting the need for confidentiality under certain conditions.

The Panel report also considered the evolving ethical and legal context for health research and expressed the hope that an appropriate balance can be struck between the promotion of health research and the protection of subjects, the public, and the environment. The Research Capability Panel report considered this to be an important concept and indicated that better understanding is needed to delineate ethical issues posed by studies of different population groups.

- Premise - The fulfillment of public expectations from health research is dependent upon the functioning of the health research continuum. To ensure proper functioning, the continuum of health research needs to be clearly defined. This definition must cover all types of research activity necessary to develop new knowledge and translate it to human health application. It must also explain how those different parts of the research continuum interact with and depend upon one another.

(The draft set of principles under this premise presented at the National Conference addressed and defined the different segments of the health research continuum, their interaction, the role of disease prevention research in relation to the continuum, and factors which should guide the investment of resources in health research. For the most part, public testimony here addressed only those factors which should guide the allocation of resources, with no clear consensus emerging.)

The Panel report agreed that the concept of health should neither be limited to anti-disease activities nor stretched to cover all activities which promote human well-being, but disagreed on how best to categorize the various subtypes of health research. There was general agreement, however, that the concept of science base or fundamental research should be construed broadly, without reference to any particular type or level of aggregation. The Fundamental Research Panel report also defines this type of research broadly. In addition, the Clinical Applications and Health Services Research Panel report defined the areas addressed by its Panel as follows:

- Clinical Application - the further development and assessment of knowledge for immediately practical purposes. Clinical trials, comprising the largest element in this category, are defined as research activities undertaken to assess the value and effect of prophylactic, diagnostic, or therapeutic agents, devices, regimens, procedures, etc., in human subjects. Other activities included under "clinical application" are research on the development of vaccines, other biologics, drugs, instruments, and devices. These several activities result in knowledge which may be immediately applicable to man and which may enhance the quality or duration of life.
- Health Services Research - scientific inquiry into problems associated with the actual organization, financing and delivery of health care services. Health services research has both applied and fundamental components, but is less categorical and more process-oriented than is research into clinical applications. Federally supported health services research includes both program-specific and general health services research.
- Transfer - includes the application of clinical knowledge to clinical practice. To assure that appropriate and necessary health technologies are introduced into widespread clinical practice, there must be recognition that transfer follows, as a continuum, from the results of clinical applications and health services research. This does not imply that this process is always linear. Indeed, it rarely is. Rather, feedback from clinical practice contributes to establishing priorities for applied and basic research.

The Panel report indicates that the Panel was not able to reach consensus on the question of priority-setting, but did agree as a factual matter that priority-setting within a clearly defined area of health research is less difficult than among widely divergent areas or types of research.

The Panel considered the notion of keying at least some types of research to the burden of illness as determined by various measures, e.g., morbidity,

mortality, or years of expected life lost. However, some Panel members objected that research opportunity should be taken into account in addition to burden of illness; that is, unless potentially fruitful research hypotheses have been formulated, money allocated to a burdensome illness is not likely to be well spent. On the level of macroallocation, two suggestions emerged from the Panel: (1) the health research budget should perhaps be correlated in some way with the annual national or Federal expenditure for health care; and (2) as noted above, members of the public should be consulted to ascertain their views on the most important health research priorities.

- Premise - The Federal approach to the conduct and support of health research is pluralistic. The DHEW agencies responsible for health care, disease prevention, regulation, and research conduct and fund research in support of their primary missions. The mechanisms for interaction and communication among these agencies and among other non-Federal sectors of the health research enterprise need to be reexamined, and new processes must be explored to deal with problems identified.

(Principles elaborating on this premise presented at the National Conference addressed the need for better communication between research and nonresearch agencies, the organizational responsibility for planning and funding research, and the need to strengthen the role of the private sector and international cooperation. Public testimony by registered witnesses was supportive of this premise in general, without addressing in detail the subelements.)

The Panel report indicates that the Panel did not have sufficient time to discuss this premise in detail. The Panel's primary general concern was that there be a careful coordination of scope and mission among the various DHEW agencies involved in health research. The Panel also encouraged the development of more effective mechanisms for communication of health research opportunities and results among the various DHEW agencies. There was also support for the notion that the agencies can and should perform a "matchmaking" function, bringing into contact investigators whose research could be mutually illuminating and supportive and thereby enhancing the impact of the research on the development of new knowledge and on the solution of national health problems.

The Panel was unable to develop general recommendations for the relationship of DHEW to the private sector in health research. One specific recommendation advanced by several witnesses and Panel members was that DHEW agencies supporting health research develop matching-grant programs, in which contributions of private foundations toward designated health research areas or projects would be matched by Federal support. In addition, one Panel member urged that DHEW not confine its health research focus to the American setting but consider, as well, the international burden of illness. This broadened perspective would encourage international cooperation in research.

The Health Regulation and Promotion Panel report urged joint efforts in the health research area be explored between the Federal Government and the private sector, and the Clinical Applications and Health Services Research

Panel report called particular attention to considering the role of the private sector in the conduct of developmental research. The Research Capability Panel report supported the pluralistic approach in the support of health research and noted that NIH be assigned only research and related research responsibility, not regulatory, promotion or care activities.

ADDITIONAL SUGGESTIONS IN THE UNIFYING CONCEPTS
PANEL REPORT

The Panel report agreed on the following prerequisites for a healthy health research enterprise:

- Funding and training of young investigators is essential to the future of health research.
- Long-term stability in the funding of health research is necessary, but within this stability of funding there should be sufficient flexibility to allow for a rapid response to promising new research opportunities.
- The need for a science base (or basic research) should be reaffirmed.
- Involving previously underrepresented groups in health research will, in the long run, enhance the quality of that research.
- Agency heads, including the NIH Director, should have directionary authority to respond quickly (with funds and personnel) to unanticipated research needs or opportunities.
- The need for clinical research should be reaffirmed, both as a way of testing new therapies and as a method for evaluating existing "standard and accepted" therapies.
- The importance of investigator-initiated research proposals should be acknowledged; however, a role should also be accorded to agency-initiated health research.

CONFERENCE PANEL
REPORTS

FUNDAMENTAL RESEARCH

PANEL 1: FUNDAMENTAL RESEARCHPANEL REPORTIntroduction

The Panel on Fundamental Research met for two days, the first morning and afternoon were devoted to hearing public testimony. The discussion during the evening and the following morning concerned the drafting of some additional principles, and the rewording or deletion of others. This procedure was adopted in order to foster the broadest participation of Panel members. The results, although somewhat modified in wording, are largely in support of the DHEW principles.

The public witnesses represented a number of professional societies and interests groups. Their testimony could be categorized into two general classes; one group discussed a variety of concerns of the community of fundamental research investigators and offered recommendations for improving policies and practices to enhance the environment for the conduct and support of research under Federal auspices; the other spoke largely from the standpoint of particular scientific disciplines, health concerns, or special advocacy. In the latter case, there was little sense of limitation of resources and no suggestions for differential choices. The Panel does not believe that recommendations for particular fields of research within the broad area of biomedical and behavioral research have any place in the broad principles with which it is concerned. Such matters should be considered when more detailed budgetary plans are being drawn.

In establishing principles for fundamental research, the Panel felt strongly and unanimously that it could not proceed from the assumption that, within a fixed ceiling for the support of research, fundamental research must compete with all other elements of biomedical and behavioral research. We believe that the ultimate value of fundamental research is so great and its costs so small compared with many other elements of research and, especially, compared with the costs of the medical services it is intended to improve or displace, that the stabilization of support must be expressed as a stable minimum in constant dollars with such growth as may be appropriate.

Two additional tenets form the foundation for the rest of this report:

1. Support should be given only to projects and people of the highest merit and quality.
2. Assurance of stable support for excellent and productive investigators is essential to the health of the fundamental research enterprise.

A. The Essential Role of Fundamental Research

The Panel adopted as a definition that fundamental research in the biomedical and behavioral sciences is a search for knowledge directed toward increasing our understanding of life, health, and disease. It

provides the foundation for all rational applied research and practice. Several studies have shown specifically what scientists have long accepted: that most advances in diagnosis and treatment are developed from knowledge that had been gained from research that was not aimed at that specific question. To quote from one such study (of the top ten clinical advances in diagnosis, prevention, and treatment of diseases of the heart, lung and blood vessels):

"In this study of 529 key articles, judged to be especially important for recent clinical advances in cardiovascular and pulmonary medicine and surgery, 41% reported research that, at the time it was done, was unrelated to the clinical problem it later helped to solve. Of the 529 articles, whether the scientist's goal was clinically oriented or not, 61.8% reported basic research and only 21.2% reported clinical investigations that were unconcerned with basic mechanisms." 1/

From such considerations, we conclude that:

- The essential value of fundamental research is to provide the advances in knowledge that form the science base for further progress.
- Fundamental research must be strongly and steadily supported in order to attain the means to promote the physical and mental well-being of man.

B. Allocation and Management of Resources

Applied research (e.g., drug screening and testing, technology transfer) has been, in the past, supported from the single pool of funds available for all research efforts. While funds for such applied research will continue to be essential, these needs and others (such as growing but necessary costs of institutional and administrative support) should not be allowed to threaten the stability of high-quality fundamental research. By its nature, fundamental research requires a long-term commitment; its full benefits may not be realized for many years. However, past accomplishments have consistently demonstrated that the value of fundamental research is amplified in the pay-offs achieved through its exploitation. It was suggested, although the proposal was not unanimously supported, that the funds needed for stabilization of basic research might be derived as a percentage of the gross expenditures within the health care delivery system.

The Panel believes that the allocation of support to fundamental research is best maintained by continuation of the present pluralistic system--that is, one in which most allocations are determined by the immediate and long-term relevance of such research to categorical missions, with an additional source of allocations to cover areas whose relevance to particular categorical missions may be less immediately apparent. It must be recognized, however, that allocations for fundamental research within programs oriented to categorical missions are often threatened by pressures for short-term practical application and early payoff. Since neither fundamental nor applied research can

long survive at the expense of the other, it is essential that an appropriate balance be maintained. Accordingly, we recommend that

- The Directors of NIH and ADAMHA be charged with the responsibility for monitoring the allocation of resources within the individual Institutes in order to preserve and insure the stability of this long-term commitment and to maintain vigilance against the diversion of limited resources to short-term goals.

There is a continuing need for attention to the institutional instruments through which the Federal program of biomedical and behavioral research is carried out. It must be recognized that the program is, albeit loosely, integrated at the national level, and it is vital that neither fundamental nor applied research be subject to decentralized control by incorporation into the responsibilities of local agencies for the planning of health care. At the same time, the stability of the institutions in which most of the research is carried out is essential to the success of the research program. In a system in which support is allocated largely for individual projects, it is inevitable that there will be fluctuations in the resources upon which research institutions can depend. These fluctuations can be reduced and increased flexibility gained through limited delegation of Federal resources to such institutions. A mechanism of this type, the Biomedical Research Support Grant, has been shown to provide a valuable supplement to the project grant system and has added strength and stability to the Federal program. As one of the least visible elements in the system, this mechanism has been threatened in recent years because of lack of public appreciation. We urge that the Directors of NIH and ADAMHA continue to preserve and strengthen the relatively undifferentiated elements of the national system through the mechanism of general research support.

The individual research grant has been found to be the most effective mechanism for the support of creative fundamental research. The recent decline in the funding for biomedical and behavioral research has led to a progressive shortening of the term of these project grants. This change has, in large measure, been instituted upon the recommendations of peer review groups whose concern about unstable funding has led them to wish to reconsider the progress of projects at shorter intervals in order to ensure that the limited funds are located to the most worthy projects. This trend has had two serious adverse effects: first, to increase the workload of the advisory peer review system beyond its effective capacity, and second, to place upon investigators the burden of frequent reapplication before projects can be carried to fruition.

- The trend to short-term funding of regular individual research projects led by investigators of proven competence is extremely wasteful of administrative resources and of investigator time and effort and must be reversed through a firm policy of long-term, stable funding. The recommendations that emerge from this planning effort should provide the basis for such a policy.

C. Assurance of an Adequate Balance in Fundamental Research

Recommendations concerning the distribution of support among the various fields or areas of fundamental research are the responsibility of the Directors of NIH and ADAMHA. The outcome of such recommendations are inevitably subject to alteration during budget preparation and the legislative process, not only to conform to policy established within DHEW and OMB, but also from the pressures of external lobbying groups. Nonetheless, it is important that the Directors conduct frequent reviews of the distribution of fundamental research support among the various disciplines with the assistance of the directors and advisory councils of the Institutes, ad hoc committees, and, when appropriate, outside bodies such as the Institute of Medicine, National Academy of Sciences.

- These reviews and recommendations should be based on an assessment of ongoing research and new scientific opportunities as well as availability of the required scientific talent and the perceived social need.
- The reviews should identify new areas that warrant support as well as inappropriate distribution among the areas already being supported.
- Consideration should also be given to fields of research that might benefit from inputs from a variety of disciplines including those not conventionally considered part of the medical and behavioral research spectrum.
- In addition to transmission of their recommendations to the Secretary of DHEW and the Congress, there are several mechanisms that the Directors can use to provide leadership to encourage new areas of fundamental research: initiating training programs to increase the scientific talent available in a field, convening conferences to stimulate interest in new areas judged appropriate for development, and modest use of special funding mechanisms to produce immediate and direct involvement of investigators in a new field.

D. Assurance of the Quality of Research

The experience of the past three decades has demonstrated that the peer review process--that is, the evaluation of scientific merit and promise by assembled groups of appropriately selected experts--as developed and practiced at the NIH and ADAMHA, is an effective system for assuring the quality of research. The Panel recognizes, however, that the peer review system at present has a number of problems, owing to understaffing and overloading of its members, that prevent optimal operation. The Panel commends the NIH for its study of such problems as overwork of study section members, understaffing, and high volume of paper work, and urges that solutions be found.

In current practice, regular appointed study sections assess the merits of individual research grant applications, whereas special, ad hoc study sections review large center or program-project grants. The merits of this parallel procedure have been repeatedly questioned, since there is some doubt as to whether it assures an equal depth of expertise and

scrutiny in the review process. It does not easily permit direct (immediate) comparison of center (or program project) associated grants with similar work being performed by others with individual support.

- The peer review system must be regarded as an effective, indeed essential, instrument in the conduct of research grant programs.
- Because the system is cost-effective and essential in carrying out the research missions of NIH-ADAMHA and because the regular study sections are the key element in the system, the Panel recommends that such initial review groups no longer be classified as "public advisory groups," but that a new category of consultant groups be established for this specific purpose.
- To insure uniform quality control, all research grant applications should be processed through regular study sections, which should be strengthened in number, size, and composition to permit efficient management of the gargantuan review task.
- Special study sections should be convened where necessary for review of applications for core facilities.

E. The Role of Training Programs in Fundamental Research

Although the subject of training is to be covered by Panel 4 under Research Capability, its role is so interwoven with the success of fundamental research, that we find it necessary to offer our comments as well.

Advances in fundamental research require the continual entrance and contribution of bright young scholars in the several disciplines of biomedical and behavioral research. This constant infusion of young scientists brings fresh ideas, new energy, and up-to-date education in related fields into research programs where interactions with established investigators provide an ideal setting for the emergence of new research perspectives. Many advances in fundamental research occur during the early stages of research careers. Many established investigators respond to the challenge and responsibility of training programs by sustaining their own efforts at peak levels.

The fact that not all those who enter research training will pursue life-long careers in research is not a valid argument against research training. The capability to make original research contributions cannot be assessed with complete accuracy until research experience is acquired. Many of those who ultimately do not pursue lifetime careers in research make valuable contributions to fundamental research during their period of training. An organized system of research training programs has proved to be the most effective means of attracting both well-prepared and highly selected Ph.D. candidates and young M.D.'s into the fundamental research disciplines.

- A renewed Federal commitment to research training for Ph.D.'s and M.D.'s through institutional research training grants, individual training awards of up to five years, the Medical Scientist Training

Program, and career development awards is essential to the current quality and future performance of fundamental research.

- Institutionally based training programs provide an optimal stable environment for the development of the young scientist and are essential for recruitment of the best candidates into research.
- Since many career choices are open to the best candidates for research, the provision of well-organized, carefully reviewed, and cooperatively selected institutional training programs and stable funding sources throughout the lengthy period of research training are essential to recruit the best people for future research careers.
- Individual training grants of up to five years duration are essential to allow the maturation of the young Ph.D. into an established investigator.
- In research areas that are currently undermanned, the establishment of training programs offer the best assurance that these fields will obtain adequate numbers of qualified investigators in the future.

Summary

Panel 1 members have chosen to organize their draft report on Fundamental Research under five headings:

The Essential Role of Fundamental Research

Allocation and Management of Resources

Assurance of an Adequate Balance in Fundamental Research

Assurance of Research Quality

The Role of Training Programs in Fundamental Research

Finally, the Panel in its review of the DHEW Draft Principles took particular issue with the subprinciple which states, "Basic research is surrounded by, and must relate closely to, an area of applications research." This same subprinciple evoked the most vehement comment from the witnesses. The members of the Panel do endorse the following section as they have edited it.

Principle--A national commitment to fundamental research is essential to meet the full range of the public expectations for health.

- Federal investment in fundamental research must be maintained to develop the knowledge that forms the basis, through applied research, to the prevention, diagnosis, and treatment of disease and for rehabilitation. This requires a long-term investment that provides the freedom for scientists to pursue

diverse topics that may not appear immediately relevant to practical health problems.

- This national commitment must include the long-term, stable support that is essential to the maintenance and strengthening of the base of scientific knowledge related to all the health missions of DHEW.
- The decision to fund fundamental research in a given area should be based upon an assessment of related ongoing research and new scientific opportunities.
- Investigator-initiated proposals must continue to be emphasized in the conduct of fundamental research, and must be restored to their earlier position as the primary mechanism in the allocation of funds. This mechanism allows for the maximum expression of individual ingenuity and competence in the formulation of research strategies, and therefore ensures a freshness and diversity of approach that would be difficult to evoke by any other means.

1/ Comroe, J.H., and Dripps, R.D., The Top Ten Clinical Advances in Diagnosis, Prevention and Treatment of Diseases of Heart, Blood Vessels and Lungs - Why and Where They Occurred. Report under Contract 1-HO-12327 from the National Heart and Lung Institute and Grants from The Commonwealth Fund and The Burroughs Wellcome Fund.

CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH

PANEL 2: CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH

PANEL REPORT

(The following document has been drafted by the Panel on Clinical Applications and Health Services Research. (A list of the membership of the Panel is attached.) This document has been compiled on the basis of: 1) a draft proposal of DHEW health research principles provided by the Department's staff; 2) public testimony received on October 3 and 4, 1978; 3) written testimony submitted and made available to the Panel; and 4) deliberations of the Panel. Necessarily, we have worked under relatively severe time constraints. We view the attached document as one that can and should form a basis for a continued consideration of the DHEW health research principles related to clinical applications and health services research.)

The members of this Panel sought to define a base of knowledge in support of those missions of DHEW which relate to improvement of health care, to prevention of disease and to regulation of health services. To deal adequately with the principles related to research into clinical applications and health services, it is essential to keep certain definitions in mind. Clinical science is the clinically oriented portion of the basic science knowledge base which shades into another part of the continuum of knowledge development, which is more rigidly defined as clinical application. Clinical application is the further development and assessment of knowledge for immediately practical purposes. Clinical trials, comprising the largest element in this category, are defined as research activities undertaken to assess the value and effect of prophylactic, diagnostic, or therapeutic agents, devices, regimens, procedures, etc., in human subjects. Other activities included under "clinical application" are research on the development of vaccines, other biologics, drugs, instruments, and devices. These several activities result in knowledge which may be immediately applicable to man and which may enhance the quality or duration of life.

Health services research is scientific inquiry into problems associated with the actual organization, financing and delivery of health care services. Health services research has both applied and fundamental components, but is less categorical and more process oriented than is research into clinical applications. Federally supported health services research includes both program-specific and general health services research.

Transfer includes the application of clinical knowledge to clinical practice. To assure that appropriate and necessary health technologies are introduced into widespread clinical practice, there must be recognition that transfer follows, as a continuum, from the results of clinical applications and health services research. This does not imply that this process is always linear. Indeed, it rarely is. Rather, feedback from clinical practice contributes to establishing priorities for applied and basic research.

Funding should not be diverted from fundamental research to provide

resources for the needs of clinical applications, applied health services research, or transfer activities. Funding of these latter activities by the Federal government should include a strategy which not only relates to health care expenditures, but also to providing incentives to State and local governments, to the voluntary sector, and private industry to share appropriately in the costs of these functions. This funding strategy should not be to the exclusion of the continued Federal commitment, which should include a strengthening of the Department's pluralistic approach to the support of applied research.

The Panel recognizes that the health research continuum must include developmental research. Here, basic observations are translated into preventive, diagnostic and therapeutic methods. While the majority of fundamental and clinical research is funded through NIH, private industry has traditionally accepted the primary responsibility for developmental research. In this area, industry has expertise and resources. The role of private industry is, therefore, essential in the health research continuum. Strong interactions between agencies of HEW and private industry should be promoted to insure optimal utilization of new information.

Principle--To improve the quality of health care, prevent disease and contain health care costs, the health care system requires, in addition to new knowledge development at the fundamental level, the support of applied problem-oriented health research.

- o The Department of Health, Education, and Welfare should design a strategy of support for health research that fosters the development of a knowledge base essential to the solution of problems in disease prevention, health care and regulation. Fundamental research as well as the application of fundamental research to the solution of clinical problems is and should continue to be addressed. There is a need to develop a systematic way to meet the needs of health regulatory agencies for specific knowledge.
- o The NIH and the ADAMHA have a responsibility to assist regulatory and policy-making agencies when called upon to do so, but only when the request falls clearly within the mission of these agencies. The dollar and manpower costs to the NIH or the ADAMHA in complying with requests for assistance from other agencies must be recognized.

In addition, the Congress and the Executive Branch should recognize that the needs of the regulatory and service agencies for mission-related, applied research should be supported through provision of funding within the agency budgets. This should assure the most effective approach to the particular problems of the agency. Coordination of and dissemination of the required knowledge for the various agency functions should be provided through interagency committees responsible to the Office of the Secretary.

- o The validation of methods of prevention, diagnosis and therapy before their general introduction into the health care system must be reasonably assured, and indications for their use in health care

practice identified. This includes the validation of such methods in terms of efficacy and safety prior to the transfer to widespread clinical practice. After introduction, monitoring programs should be constructed to provide the data base for evaluative measures of both costs and benefits of the use of new methods of prevention, diagnosis and therapy in actual practice. This should be the function of a strengthened national effort in health services research and technology assessment within the scope of the Office of the Assistant Secretary for Health.

- The dissemination of health services research results to providers of health services requires more emphasis.

Consensus development approaches for providing information and technical transfer should be strengthened to assure the appropriate involvement of all constituencies relevant to the specific health technology. Adequate concern for premature introduction of new health technologies is as essential as concern for the expeditious application of appropriate and necessary advances.

- Current measurement techniques in the health services research field are often inadequate for investigating and evaluating the effectiveness of health care. Fundamental research in statistical, epidemiological, sociological and economic methodology needs to be supported to provide improved measures and quality statistics on disease prevalence and incidence, morbidity and mortality, disability prevention, health practices, behavior, enhancement of quality of life outcomes, and the organization, delivery, and financing of health care services. Improvement in these methodologies requires a long-term commitment. This commitment includes the support of training of sufficient numbers of qualified researchers, such as biostatisticians, epidemiologists, demographers, sociologists, health economists, health systems analysts, etc. Support for methodological research should be at a reasonable level independent of support for specific health programs. In addition to methodologic research aimed at developing investigative techniques, research into the new methodology and technology for application to delivery of health services needs to be supported.
- A strategy should be adopted for funding health research that includes provision for support of clinical applications, clinical trials, and applied health care and health services research that focuses directly on program missions. These programs often involve relatively high cost and long-term, multi-year commitments. This support should be as direct add-ons to agency budgets where an adequate and available science base exists. Recognizing that resources are limited, criteria for establishing priorities for such activities are necessary. These criteria include: the state of the science base related to the effort; the feasibility of the effort based on the state of knowledge and available resources; the potential impact of the trial on research, health care, the burden of illness, and various ethical considerations. Concerning

the source of such add-on funds, consideration should be given to acquiring these funds from the health care dollar or, alternatively, from general revenues obtained through the Congressional appropriations process with specific mechanisms for assuring continuity, such as multi-year research budgeting.

- Certain applied research areas or disciplines, such as epidemiology, biostatistics, toxicology, and nutrition, contain a core of activity which is distinct from both research in the basic sciences and development of clinical applications. The defining characteristics of this core research are its multidisciplinary nature and the general applicability of findings to a number of problems or targets. While normally considered applied, these disciplines must have an appropriate priority for stable funding and protection from diversion of resources into short-term, targeted or goal-oriented research.
- The scientific merit of clinical investigations, clinical applications and health services research is a necessary condition for support. All departments and agencies sponsoring health research should employ procedures to assure scientific merit through peer review including nongovernmental personnel representing appropriate disciplines. Such procedures should apply to all projects involving substantial expenditures.
- The Panel agrees that DHEW's present pluralistic approach to the support of both clinical applications and health services research must be maintained, and that the planning and coordination among DHEW agencies need to be strengthened. A pluralistic approach within the Department is required because of sheer size and complexity and because of varying missions of the agencies and their research needs. Accepting a pluralistic approach, however, leads to the potential for fragmentation, overlap and duplication of effort, as well as the possibility of lack of effective transfer of information and results. These factors all underscore the need for integrated planning and coordination within the Department. Specifically, the Panel proposes the establishment of a Secretary level committee to include representatives of all agencies involved in applied research. This committee would evaluate priorities, avoid gaps and duplication of effort, and generally monitor the Secretary's mandate to provide an applied research capability appropriate to the Department's needs.
- Federal health services research activities are vested in the several agencies which have mandated programs. Together they serve the health services research community. General health services research provides the framework for research outside the context of particular programs. General health services research is primarily the function of the National Center for Health Services Research, and its function should be maintained. The Center would be the primary operational arm of the committee.
- While a coordinated Department research effort is essential, it is clear that operating service agencies require an analytical

capacity which takes priority from the immediate needs of their programs. Authority for such program-specific research should be within each agency, and support for this research should be an integral part of its operating budget and not necessarily a part of the general applied health services research activities of the Department.

HEALTH REGULATION AND PROMOTION

PANEL 3: HEALTH REGULATION AND PROMOTION

PANEL REPORT

"Human knowledge and human power meet in one; for where the cause is not known the effect cannot be produced. Nature to be commanded must be obeyed. . . " 1/

We do not accept the premise that resource limitations preclude significant expansion of the health research budget. That is a political judgement, not a reflection of economic necessity. With a health care budget estimated at \$200 billion for 1978, the current research expenditure is little more than 1% of that total, a miniscule investment in relation to the size of the enterprise whose effectiveness rests upon it. Health research, basic, applied and related to the efficacy of preventive, therapeutic and regulatory services, provides major hope of improvements in the public health and in cost containment. It is penny wise and pound foolish to economize on the investment in obtaining the knowledge which can permit effective action for better health. For example, the health care costs entailed by unwarranted, hazardous and costly surgical and diagnostic procedures exceed by an order of magnitude the size of the current investment for all health research. Therefore, we propose as the first operating principle:

Progress in health regulation and promotion require an increased commitment of Federal funds for health research, both basic and applied, including research on the effectiveness of health services, on the means of monitoring the health care system, and on establishing standards for health services. At both fundamental and applied levels, the behavioral sciences are an integral part of an effective health research effort.

We next turn to a consideration of regulation as it relates to those agencies which must make socially and medically important decisions based in large part on scientific information. Protecting the public health from diverse environmental exposure requires control options ranging from information and education to regulation at the Federal level. For each of these stages, a sound knowledge base is essential if the controls are to be appropriate and effective. We are now fully in an era where it must be recognized that no chemical or biological agent is totally "safe." The consequence of this recognition is that we must learn how to balance risk against benefit. This demands that we be able to make quantitative estimates of benefit as well as risk, a decision-making activity that in itself requires an intellectual as well as a factual base. Therefore, we propose as our second set of operating principles:

The knowledge base for regulatory action will require a variety of information sources from fundamental research through short-term highly applied research in immediate and direct support of regulation and of monitoring for compliance. The NIH should continue to be the major

1/ Francis Bacon: Novum Organum (1620): from the third aphorism "Concerning the Interpretation of Nature and the Kingdom of Man."

source of basic biomedical research.

In addition, several of the Institutes, NIEHS and NIOSH in particular, have a special role for adding to and exploiting this resource of basic knowledge for the purpose of improving our understanding of environmental and occupational hazards.

There is an equally pressing need at the regulatory level for directly applied research. Such research resources should be responsive to the regulatory agencies themselves for the transitional and short-range research necessary to convert limited information into scientifically acceptable regulatory and control options. However, we do not believe that basic research is best carried out within a control agency itself.

We call attention in particular to the importance of developing comprehensive and reliable measures of the degree of improved health and well-being that accrues to individuals protected from deleterious occupational and other environmental hazards. Health protection requires public information and education as well as regulation. In all these stages, a sound knowledge base is required if regulatory actions are to be optimally effective.

There are other regulatory agencies that address other aspects of health sector performance, e.g., HCFA, HSA's, OSHA, hospital-rate regulation agencies and the like. The Federal health research establishment has a responsibility to assure that these agencies have the information necessary to discharge their functions effectively and responsibly. In addition to the information yielded by biomedical research, data yielded by research on the performance of health care delivery systems and on the health care financing system and other aspects of health services research is essential. Health policy frequently is informed by the results of cost-benefit and cost-effectiveness analysis. There is need for research to develop an appropriate conceptual framework for the measurement of the benefits which accrue to life-saving and morbidity-reducing activities. Therefore, we propose as our third operating principle:

A fixed and adequate percentage of the budget of health care agencies should be set aside for the purpose of acquiring a reliable data base which will permit determination of the efficacy of the services being purchased. We propose this approach in order to emphasize the importance of health services research as well as the fact that it should not be done at the expense of support for the basic research effort of the NIH and ADAMHA.

Government-supported research must have a strong orientation toward improving the quality of the nation's health and the effectiveness of its health services by developing knowledge bases that support prevention, delivery, regulation, standard-setting, and cost control. This indicates a sizable need for increased research in biostatistics, epidemiology, health behavior, health services, environmental health and nutrition. In response to this priority, we propose a fourth set of operating principles:

There should be greater support for institutional and project research within universities for the areas of biostatistics, epidemiology,

behavioral sciences, environmental health, and occupational health.

For such research to succeed, there must be assured funding for the education of investigators and for the education of the potential users of research information (such as regulators and planners).

Stable support is necessary to assure that the field remains attractive to capable researchers and to sustain a continuous national effort in health services research.

Among the approaches to health protection, large-scale epidemiologic studies are vastly underutilized. Such investigation can point to the presence and effects of environmental hazards, unanticipated effects of drugs, patterns of illness and of illness treatment that have better or poorer outcomes, the appearance of new diseases or greater incidence of known diseases, factors correlated with better health and other epidemiologic findings. Therefore, we propose as the fifth principle:

We recommend an expanded effort to support large-scale epidemiologic studies. Such studies should include the natural history of disorders and the identification and quantification of both risk factors and protective factors.

We were equally concerned with the second aspect of our charge: health promotion. Public policy must be aimed at improving health by applying effective preventive measures among both individuals and populations. Such measures may involve altering nutrition patterns, environments, lifestyles and behavior to reduce the risk of disease, disability and premature death. To be effective, health promotion must involve a concerted plan to produce changes in governmental policies, in the behavior of agencies and institutions in both the public and private sectors, in the selection, training, remuneration and values of health providers as well as changes in the behavior of individuals. Therefore, we propose as our sixth set of principles:

There should be a higher priority for research (much of it basic) to determine the most effective means of health promotion and disease prevention, the best ways of transmitting information to lead to changes in behavior, and the circumstances under which specific measures can be most effectively directed to different populations.

A better balance should be sought between research directed at prevention and research directed at treatment. This is not a question of basic versus applied research. Indeed, in many instances, only basic research can yield the knowledge necessary for prevention.

Research is needed to provide broader and more accurate descriptions of well-being and effective social function as well as more accurate assessment of the burden of illness than is provided by the conventional measures of morbidity and mortality. Such methodologic advances are essential if we are to be enabled to assess accurately the effectiveness of health promotion measures.

Public efforts to improve health by altering institutions, environments,

lifestyles, health services, nutrition, and behavior to reduce the risk of disease and disability require more reliable data bases for such decisions. Although such measures may in the long run be less costly than emphasis on curative approaches, we emphasize that the major rationale for such measures is the increase in well-being, not cost savings.

Regulation is one kind of strategy which seeks to improve the performance of the health sector. In many instances, educational strategies may achieve the same objectives. Research addressed to "regulation" should include attention to the potential yield from "non-regulatory" strategies.

Research for health promotion must include programmatic approaches that stress the total range of interrelated health conditions rather than categorical illness alone.

It is in the nature of the task of health regulatory (FDA, OSHA, for example) and health monitoring agencies (CDC, for example) that urgent problems arise unexpectedly and cannot be foreseen in annual budgets. Examples might be legionnaires disease or polybrominated biphenyl contamination of cattle feed. It is essential that a pool of flexible unassigned research funds be available: to add personnel to agency staff, to contract out specific studies or to initiate longer run investigations where basic knowledge is not available. Therefore, we propose as our seventh principle:

The Secretary of HEW should be empowered to maintain an undesignated research fund to be allocated by an interagency coordinating committee with representation from NIH and the regulatory and service agencies. Upon request by the operating agency, and in relation to the urgency and the merit of the proposal, the coordinating committee would assign sufficient funds to accelerate the pace of investigation.

Finally, we note that there may be a far greater potential than has so far been exploited in the health research area for funding through partnership programs between the Federal government, on the one hand, and voluntary health agencies, philanthropic foundations, State and local governments, and industry, on the other. Such joint efforts should be explored, with appropriate attention to necessary safeguards so that the public interest takes precedence over parochial and self-serving concerns.

We reiterate our conviction that effective action for health regulation and health promotion rests, in the first instance, on an adequate knowledge base for which sustained and systematic research is necessary. Further, the costs of that research, though not inconsiderable, are nonetheless quite small in relation to health care costs. But knowledge alone is insufficient. There must be a national will to put that knowledge to work: by making the difficult decisions to act on what we know.

RESEARCH CAPABILITY

PANEL 4: RESEARCH CAPABILITYPANEL REPORTIntroduction

The Panel has read with care the Draft Health Research Principles of DHEW, the Preliminary General Themes of Public Suggestion for DHEW Health Research Principles, and the Summary of Comments from Other Federal Departments and Agencies. We have heard testimony and have had an opportunity to view papers from individuals, most of whom represented important groups concerned with the nation's research capability, and all of whom spoke with conviction and good will.

Although many different views were expressed about specific areas of emphasis, we heard no serious dissent from the draft DHEW Principles of Research Capability. We give general endorsement to all other than item 3 on page 16 which, as we understand it, does not fit into our concept of health research except as it may be interpreted as referring to the excellent science information programs conducted by the National Library of Medicine.

We are keenly aware of the central role of the Federal Government in creating and maintaining the health research capability of the nation. We have tried to develop principles that will be helpful to others in setting goals and ultimately in developing budgets that will reflect different choices between alternative opportunities.

We do not agree with the necessity nor the desirability for viewing health research dollars as a fixed budget for the next five years, even if it is to receive increments commensurate with inflation. The Panel recognizes and supports the need to examine with care the changed conditions of a world of increased resource constraints. Biomedical research cannot, and should not, be immune from such constraints. However, the consideration of the appropriate level of future support should include both awareness of the unique Federal role in this field and the potential to achieve important national goals with modest investment. It is primarily through appropriate research in the causes, prevention and treatment of disease that cost containment can be achieved.

We have been overwhelmed by the wealth of opportunities for preserving, improving and creating research capacity. Ways have been suggested to build capabilities both around problems that need solving and around techniques that hold promise. Rather than merely commenting on each of the principles set forth by the Department, we have chosen to amplify, extend and augment them by stating our own views in our own words. In doing so, we felt better able to express our own emphasis to our own sense of priorities.

The most important principle, the one that guided our discussion, is the unanimous conviction that only research of the highest quality is worth doing. High quality has been the key to past successes and will inevitably be essential for future advances. Consistent high quality has been achieved through the use of review panels of outside experts. The continued success

of the health research effort depends on maintenance of the peer review system and its extension in other areas where applicable.

We discuss health research capability under the following headings:

- A. Human Resources
 - B. Institutional Resources
 - C. Physical Resources -- Laboratories, Buildings, Equipment and Information Systems
 - D. Animal Resources and Populations for Health Services and Other Research
 - E. An Appropriate National Climate
- A. Human resources are the most important ingredient for research capability.
- 1. Human resources must be maintained.
 - Investigators of proven productivity should be able to depend on stable research support during their demonstrably active careers. Perception of the esteem in which the creative biomedical and behavioral scientist is held, as witnessed by the availability of support for good work, is an inducement to the talented young investigator to enter upon a similar career.
 - Further opportunities for careers in research must be kept competitive with alternate roles in practice, industry and administration.
 - 2. Human resources must be renewed.
 - Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and medical careers. We urge support for education and research training at both the pre- and postdoctoral levels in order to continue a steady flow of young investigators from whom so many of the creative ideas will come.
 - There must be a regular reassessment of the needs for training for research careers in the biomedical sciences. The annual or biennial reports of the National Academy of Sciences should receive appropriate consideration and serious attention as goals are set.
 - It is felt that additional studies are needed of the future availability of junior faculty positions to evaluate the problems that will arise in the next 10 - 15 years because of decreasing college enrollments and changing retirement patterns.

- The employment model used in estimating needs for numbers of training individuals and disciplines for biomedical and behavioral investigators requires expansion into a more complete job market study. Such a model should be given serious consideration so that all avenues of needed support relating either to numbers or disciplines are left open and as broad and accurate as possible.
- Certain ethnic minorities (Blacks, Chicanos, Puerto Ricans, and Native Americans) are underrepresented in the health field generally, including research. Programs to encourage the research training and research grant support of minority investigators and minority institutions such as the Minority Biomedical Support (MBS) Program and the Minority Access to Research Careers (MARC) Program of the NIH should be continued and expanded. A second suggested mechanism is the development of special institutional grants to minority institutions which show high promise for contributing to the national research enterprise and which will facilitate the entry of such institutions into the national mainstream of biomedical research.
- An explicit effort to encourage acceptance of minority trainees in established institutions should be encouraged. Individual fellowships should be available for this purpose.
- Special programs designed to enable capable young women to compete successfully for research support should be carefully designed. These programs are required both for the woman with a young family and for those with high potential and/or research training who, for one reason or another, have left the field and wish to reenter the biomedical or behavioral research laboratories.
- Recruitment of young scientists to areas of greatest national need and greatest research opportunity should be encouraged. Mechanisms should include the opportunity of changing plans rapidly as new opportunities develop.
- Individual research career development awards, as well as individual and institutional fellowships, are good mechanisms to provide such research training. New and young investigator and academic awards may be used as well.
- Able young investigators should also be given freedom to develop their own approach and to pursue the leads in research that they perceive as the most productive. This should also include the possibility of changing plans rapidly as new opportunities develop.
- It is essential to provide opportunities to individuals who have just obtained health professional or research degrees to embark on academic and/or Federal research careers.

- Clinical research so important to the nation's health depends upon the providing of opportunities for promising clinically trained individuals with aptitude for research to develop into independent investigators as well as for Ph.D.'s to enter clinical research disciplines.
 - Programs to support interdisciplinary, collaborative research must be made available, where appropriate, to utilize the broadest training approach to difficult problems. Some of these opportunities must be in clinical environments.
3. Adequate opportunities to obtain research grants should be available to young investigators.
- Too much money, relative to the requirement of young scientists, has gone into targeted research. For various reasons, including funding problems and other pressures, the most highly productive and creative period for most scientists is 10 to 15 years (more or less, with notable exceptions). We cannot afford to allow these early years of the brightest men and women to be fallow. In recent years, research grant proposals of young investigators, scientifically rated very highly, have sadly gone unfunded. If this trend continues, we will dry the wellsprings of scientific progress.
 - Training grants and some highly targeted programs are also helpful to assure a continuing supply of young scientists and the development of some areas of research. However, proposals for these programs should be scrutinized and weighed with particular vigor to avoid waste and, therefore, to insure the opportunity for great discoveries by young investigators and the integrity and vitality of the institutions where such scientists are likely to thrive.

B. Institutional resources.

1. Federal research objectives depend critically upon the health and vitality of the institutions in which the research is performed. The creative nature of research requires an ambience of intellectual freedom and scientific integrity. It is imperative that the relationships between agencies and branches of the Federal government and the research institutions be more fiduciary than adversarial, that energies and money to be dissipated in friction but rather ensure a spirit of inquiry.
- Fair and adequate payment for indirect costs generated by Federal grants is essential to maintain institutional stability.
2. There is also a dire need for a significant, reliable institutional support program for sponsors of extramural research, especially in academic institutions. This support, predicated upon the magnitude of research conducted, should involve minimum constraints to sustain the stability and flexibility essential for research,

especially to facilitate the launching of young investigators. Some institutions undoubtedly will use such support more effectively than others, but without such support all research institutions will decline. It is in the external nature of research that some risks must be taken. When one is certain of the outcome, no research is necessary. Problems vary among institutions and at any institution with time. A measure of flexibility is essential. Grantee institutional response, too, must be intelligent, rapid and flexible to eliminate the risk of promoting intellectual sterility or paralysis.

3. Meticulous defense of the enormously productive intramural programs of NIH is a priority of first magnitude for the entire country and, indeed, the world. The intramural programs should continue to be a conscientious, non-partisan and central concern of all who value and share the fruits of biomedical and behavioral science. It is appropriate that intramural programs also undergo periodic rigorous peer review from outside consultants similar to that afforded extramural programs.

C. Physical resources -- laboratories, buildings, equipment and information systems.

A series of significant facts should be recognized from which are developed several pertinent principles. The first is that the adequacy of physical facilities and equipment is a major determinant in the productivity of capable scientists. Second, in research institutions throughout the country, there exists a cohort of aging facilities which, in the foreseeable future, will require renovation, rehabilitation or replacement. In addition, major equipment is in many instances becoming obsolete.

Third, research because of its dynamic character regularly requires new types of supporting resources. Fourth, the data on the status of the nation's health research facilities and equipment, as currently available, are insufficient for policy development at the national level. Lastly, health research, especially in the basic biomedical sciences, is unusually dependent on Federal support.

These considerations suggest the following principles:

- There should be promulgated a realistic national policy designed to assure the adequacy of the physical facilities and equipment which are necessary for the successful prosecution of research in the various fields contributive to advances in health.
- Essential to the development of that policy is the availability of aggregated data which would enumerate the important characteristics, such as type, size, age, condition, location and ownership of existing facilities. Provision should be made for periodic updating of these data. Appropriate inventories of major pieces of biomedical research equipment should be maintained, certainly at an institutional,

and possibly at a Federal, level. It would be useful to know what DHEW's extramural capital expenditures in biomedical activities have been for the past 10 years. The trend could be illuminating.

- The degree of Federal involvement in health research places on the Federal Government the primary responsibility for monitoring the adequacy of these facilities and for the development of a strategy which will assure such adequacy. That strategy should incorporate appropriate expressions as to collaboration between the Federal and non-Federal sectors as well as incentives for the most efficient provision, usage and maintenance of these resources. It should be recognized that the provision of new or additional facilities and items of equipment may, at times, be more cost-effective than efforts at reallocating or rehabilitating existing resources. Caution must be exercised at all times to avoid large and extensive record-keeping systems and other devices which could obscure or defeat the primary purpose.
- Resources should be conserved through sharing, both within and among institutions, to the maximum extent feasible. Where sharing is appropriate it may require changes in the attitudes on the part of some individuals or groups of scientists as well, perhaps, as new administrative concepts to facilitate such sharing. It is recognized that the various ways in which academic institutions govern themselves may introduce complications in the reallocation or retrofitting of space and equipment not in optimal use. The best way to enhance productive cooperation and synergism is to make grants available for acquisition of resources for which groups of investigators may apply on a peer review basis.
- Methods should be developed to stimulate greater ingenuity in the design and construction of laboratories and buildings. While recognition must be made of both general and specialized purposes, greater flexibility should be a hallmark of future construction, given the characteristics of changing requirements of research, high costs and long life expectancy. Other considerations, such as energy conservation and lowest possible maintenance costs, should also be recognized.
- The Federal Government should develop a realistic means of permitting a depreciation allowance for federally constructed facilities and major items of equipment to be counted in the negotiated indirect cost base for institutions. This would be in keeping with regulations pertaining to Hill Burton facilities and would greatly assist the institutions in the proper maintenance of research facilities and equipment.
- Of major importance is the stability of the continued support and expansion of health science libraries and other biomedical communication resources. Provision must be assured of the

intellectual and physical means for dissemination of knowledge to scientists as well as practitioners. Needed are both relevant research in the information sciences and the application of the most cost-effective methods currently available.

- Proper instrumentation is essential to science. The aging and obsolescence of much of the nation's scientific equipment must be corrected and the equipment kept modern. The development of biotechnology, including computer facilities, demands increased attention.

D. Animal resources and populations for health services and other research.

1. Animal resources.

Performance of fundamental biomedical and behavioral research and of much targeted research aimed at understanding of, and providing therapy for, a wide range of specific human diseases requires the ready availability of pertinent experimental animal homologs of disease states identical with, or similar to, specific human pathological conditions. The need for these experimental animals has increased, and will continue to increase, because of recent ethical restrictions on use of human subjects in research.

- Federal guidelines and legal standards have been established for maintaining humane and environmentally sound conditions, but many qualified research institutions cannot comply with the rules because they are limited to inadequate, obsolescent research animal facilities. Grants for improvement and new construction must be continued and expanded.
- Because well-characterized, genetically controlled stocks are resources for research equal in importance to libraries and scientific communication, we must expand support for breeding, and base-line characterization of needed research animals, including, in addition to experimental mammals, pertinent marine organisms, invertebrates, and specialized-use genetically controlled stocks. The current and near-future shortage in primate supply dictates the search for alternatives to large-scale use of primates. We must continue maintenance of endangered genetically controlled stocks, including collection of viruses and bacteria, protozoa, nematodes, algae, fungi, higher plants, insects, amphibia, birds, and experimental mammals with appropriate concerned geneticists as curators. It is also essential to support development of new animal homologs of human diseases.
- For increased efficiency and decreased space and expense, the potentialities for preservation of stocks of organisms in the dormant state (cryobiology) should be explored, and reliable methods should be developed for frozen-maintenance centers. Research cooperation between investigators and between institutions should be encouraged to ensure the best

utilization of these scarce and expensive research tools.

- We should promote cooperation among agencies (including components of the NIH) for the maintenance, as stated earlier, of needed stock. Because proper long-term maintenance of each type of organism is costly, we should encourage research cooperation between investigators and between institutions to ensure the best utilization of these scarce and expensive research tools. This scientifically important effort is essential for mammalian research on aging and late-developing diseases.

2. Populations for health services research and the protection of research subjects.

The increased concern for, and awareness of, the need to establish appropriate protection of human and animal research subjects have brought about a welcome improvement in ethical standards for such research. However, a profusion of paperwork, procedures and an increase in concern about legal liability have also occurred during the past few years, with a sometimes chilling effect upon important research involving human subjects. Local science research should continue to seek answers to these dilemmas and is necessary if biomedical and behavioral research involving human and animal subjects is to continue in the future.

Therefore we propose these research principles:

- Research involving human and animal subjects should be conducted in accordance with the highest ethical standards while allowing the continuing pursuit of essential research.
- Better understanding is needed to delineate those ethical issues posed by studies of different population groups, as for example, research involving children, the mentally disabled, prisoners, and groups with different value systems.
- New or changed therapeutic modalities should be introduced into general use in ways which provide assessment of their effectiveness.
- Local institutional review boards have functioned well to achieve a balance between the need for high ethical standards and essential research. Great care must be taken to preserve the structure of these boards and to avoid additional and often contradictory mandates from agencies within DHEW.

E. An appropriate national climate.

For better or for worse, the Federal Government has assumed almost total responsibility for large segments of the nation's biomedical and behavioral research needs. It would be foolhardy to suggest that support for national security or certain of the Federal regulatory responsibilities must compete equally at the Federal level with other

national desirables. Similarly, there is an added dimension of Federal responsibility in biomedical and behavioral research because of the almost complete Federal dominance in this area. This is not true in other areas of domestic involvements, e.g., education, welfare, social security, the organization and delivery of health services, agriculture, and the physical sciences. In these areas the Federal responsibility is a shared responsibility.

1. To further the acceptance and significance of the research principles and five-year research plan, it is recommended that there be embodied in legislation a declaration of the national policy and national objectives of the Federal role in health research. This legislation should authorize the overall research level, including necessary training, equipment, facilities and other support resources, for the five-year period -- including subauthorizations. The subauthorizations for individual institutes and other major health research programs should be expressed in current dollars in such a way as to avoid erosion of the research plan by the ravages of inflation and should be continued uninterrupted should there be a delay in extending the legislation at the end of the five year period. This legislation should provide a basis for consensus between the Executive and Legislative branches, the research community, and the public as to the Federal role in health research and an appropriate level of activity. This should provide an opportunity for stabilization of support and significantly reduce uncertainty and interruption of productive research.
2. Fiscal accounting procedures appropriate to physical products are not applicable to weighing ideas, reasoning and the imprecisely predictable explorations of the mysteries of nature. Peer review of original and competing grant applications as well as application for continued support is, in the truest sense, productivity accounting of the highest order. Honest fiscal accounting is of obvious importance and institutions receiving awards must maintain accountability but, in the traditional sense of American justice, must be presumed innocent until proven guilty.
3. A problem that has increased over the recent past has been a shortening of the funding period for grants from many agencies. It is essential that funding be provided for longer periods of time to provide stability of support and facilitate the research process. In the current period, all too often investigators are forced to spend immense amounts of time preparing renewal applications, even on the highest quality grants. Many believe that a return to the longer funding cycles would be one of the best ways to improve the research climate.
4. We are entirely in favor of conducting health science planning and procedural sessions openly, as they are of marked national significance. However, research protocols prepared by scientists deserve special consideration and perspective. The lifeblood of a successful scientist is his ideas and the opportunity to carry them out. Therefore, documents describing those ideas, such as research

grant applications, deserve the protection of confidentiality. In addition, it is important to avoid inadvertent or premature disclosure of potentially patentable ideas whose eventual development could have impressive national benefits. Furthermore, unless scientific review deliberations can be conducted in an atmosphere which fosters the most candid and searching examination of proposals, the public interest is ill served.

5. To assure effectiveness, productivity and objectivity of the health research assigned to the National Institutes of Health, it is proposed that the NIH be assigned only research and research-related responsibility. This might best be expressed as establishing boundaries for NIH which exclude three activities:

Regulation
Promotion
Assumption of long-term care

It is considered that activities in these three areas would be incompatible with the primary research responsibility of NIH, would have potential for impairing credibility as to objectivity of research performed, and would violate the major premises of the scientific method. It is recognized that the NIH must seriously consider the appropriate Federal role in support of research, and must strive to find the best approach for assuring application of results of research to solution of human biomedical and behavioral problems.

Conclusion

It has been our privilege to consider the principles underlying a proposed five-year plan for health research. We agree with the DHEW draft report that "present research capability must be sustained and enhanced to assure future health gains." We would add that the commitment to high quality must underlie all our planning and all our decisions. Further, we believe that stated legislative intent to continue support will do much to enhance research capabilities by giving confidence to talented individuals that they can invest their lives in this important national effort. So, too, will it give institutions the confidence that it is worthwhile to invest resources and energy toward the same purpose. We are hopeful that the development of the proposed five-year plan will provide the necessary testament to assure confidence in the stability of national purpose in support of research.

UNIFYING CONCEPTS

PANEL 5: UNIFYING CONCEPTSPANEL REPORTIntroduction

The primary goal of this report is to reflect the views of members of the panel on Unifying Concepts concerning appropriate health research principles for DHEW. Limitations of time prevented Panel members from seeking to reach a consensus on most issues. However, several dominant themes were identified by the Panel and will therefore receive major emphasis in this report.

The Panel was aided in its deliberations by the Draft DHEW Health Research Principles, by written testimony submitted by various individuals and groups, by the oral testimony of numerous witnesses who appeared before the Panel on October 3, and by summaries of the deliberations and conclusions of other Panels. However, several Panel members clearly articulated the view that the Panel's report should not merely reiterate or react to materials and views presented to the Panel but should in addition present our own independent assessment of the issues surrounding health research.

There is one additional element in the background to the Panel's work, as well as to the Conference as a whole, which was seldom mentioned -- the Report of the President's Biomedical Research Panel published on April 30, 1976. 1/ Since that earlier Panel had reviewed and made recommendations concerning biomedical and behavioral research conducted by the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), there was inevitably significant overlap between the task of the President's Panel and the work of our own Panel. In addition, some members of our Panel had participated in the earlier process, and some witnesses were identical. We have understood our mandate to be somewhat broader and more theoretical than that of the President's Panel; that is, we have sought to consider all of DHEW rather than two agencies within it and to look more at underlying research principles than at organizational and operational questions.

I. Definition of Health Research Categorization of Major Types of Health Research

The Panel devoted limited attention to the concept of "health" which should be included in the phrase "health research." Some Panel members advocated a broad concept of health, perhaps even the WHO notion that "health is not merely the absence of disease, but a state of complete physical, mental, and social well-being." 2/ Other panelists objected that such a broad definition of health would seem to include research into ways to eliminate poverty under the rubric of "health research." If there was agreement on a concept of health within the Panel, it was that the concept should neither be limited to anti-disease activities nor stretched to cover all activities which promote human well-being.

Panel members also disagreed on how best to categorize the various sub-types of health research. In its 1976 report, the President's Biomedical Research

Panel had identified six steps in "the continuum from the development of new knowledge to the application of such knowledge in health care":

1. Discovery, through research, of new knowledge and the relating of new knowledge to the existing base;
2. Translation of new knowledge, through applied research, into new technology and strategy for movement of discovery into health care;
3. Validation of new technology through clinical trials;
4. Determination of the safety and efficacy of new technology for widespread dissemination through demonstration projects;
5. Education of the professional community in proper use of the new technology and of the lay community on the nature of these developments; and
6. Skillful and balanced application of the new developments to the population.

The DHEW Draft Research Principles 3/ repeatedly employs the "continuum" metaphor and seems to distinguish three types of research:

(1) fundamental research; (2) applied research, including research on clinical applications; and (3) health services research. A third categorization seems to have been adopted by at least some parts of NIH: (1) science base; (2) application, including clinical trials; (3) transfer; and (4) training.

While there was no clear consensus within the Panel concerning the best set of categories to use or even concerning the optimal metaphor to employ (continuum, circle, foundation and superstructure, or feedback loops), there was general agreement that the concept of science base (or basic or fundamental research) should be construed broadly, without reference to any particular type or level of aggregation. In the words of Dr. David Hamburg, "Fundamental research applies to all levels of organization: molecular, cellular, organismic, and population." The Panel regards this broadened conception of the science base as one of its major contributions to the discussion of health research principles.

II. Rationale for Federal Support of Health Research

One issue not raised by the DHEW Draft Research Principles but discussed at some length by our Panel was: Should the Federal government be involved in the support of health research at all? Having "thought about the unthinkable," most if not all members of the Panel agreed (1) that the Federal government should support health research but (2) that the rationale for such support should be clearly presented to the taxpaying public rather than merely presupposed.

Several possibly complementary rationales for Federal support of health research were considered by the Panel. A historical rationale is the desirability of democratizing the support of science; on this view, the

government in a democratic society can and should assume the responsibilities previously borne by the Church, royalty, the aristocracy, and private foundations. An esthetic rationale was also considered by the Panel: good science is an art form, and the development of new knowledge is an intrinsically valuable activity which should be supported by the society. A third possible rationale is more defensive in character, namely, that since DHEW is paying larger sums each year for health care through Medicare and Medicaid, it should allocate at least some of its resources to research which may lead to more effective and more economical health care. However, there was general agreement among Panel members that it is the results of health research -- especially in terms of decreased morbidity and mortality -- which constitute the strongest general rationale for Federal support of that research. Even here, a caveat was entered by some Panel members: research does not necessarily or automatically lead to improved health; rather, it allows for more informed decision-making on health matters by the citizenry.

The Panel also examined the rationale for specific categories of research. It was generally agreed that the development of a science base (or basic research) is the most difficult type of health research to justify to the public precisely because it seems more remote from the health-related goals of such research. The metaphors of a long-term "investment," as suggested by the DHEW Draft Health Research Principles, 4/ may be useful in communicating to the general public the value of basic research.

III. Public Understanding of and Participation in Health Research

The correlative themes of public understanding and public participation were virtually absent from the Report of the President's Biomedical Research Panel. In our Panel's view, the inclusion of these themes in the DHEW Draft Health Research Principles marks an advance over the earlier report and an acknowledgement of the changed social context in which health research must now be carried out.

The Panel members were in general agreement that the scientific community has not, in the words of the Draft Principles, adequately "communicate(d) to the public the nature of the scientific process, its promise and limitations." 5/ Increased efforts to present health research in general as well as specific areas of health research to the increasingly sophisticated public are strongly supported by the Panel. Panel members were confident that greater public understanding of health research will in the long run promote rational decision-making and increase public support for such research.

Whether or not the public understanding is enhanced, it seems clear that at least some segments of the public will press for increased participation in the health-research enterprises. Public membership on National Advisory Councils, Institutional Review Boards, and Institutional Biosafety Committees; the recombinant DNA debate; and the work of the National Commission for the Protection of Human Subjects and the DHEW Ethics Advisory Board are all indicators of the trend toward increasing public participation. However, there was insufficient time for the Panel to discuss thoroughly the optimal manner and extent of public participation.

Negatively, it was agreed that the scientific merit of scientific proposals should be evaluated primarily, or even exclusively, by scientists expert in the area of the proposed research rather than by members of the public. Positively, at least one Panel member advocated that members of the public participate directly in helping to set health-research priorities at the macroeconomic level.

In the Panel's view, a general principle which is relevant both to public understanding and public participation is that the decision-making process in the formulation of health research policy should be both open and accountable. This principle implies that information about the factors considered in making decisions should be readily available and that decision-makers should be willing to justify and take responsibility for their decisions.

IV. The Health Research Enterprises

The Panel was generally agreed on the following prerequisites for a health research enterprise. Prerequisites receiving the most discussion and support within the Panel are listed first:

1. The funding and training of young investigators is essential to the future of health research.
2. There should be long-term stability in the funding of health research, but within this stability of funding there should be sufficient flexibility to allow for a rapid response to promising new research opportunities.
3. The need for a science base (or basic research) should be reaffirmed. Without such a foundation the entire structure of health research will collapse.
4. A tension may exist between the quest for excellence and the concern for democratization in health research. Without denying this tension, some Panel members argued that involving previously underrepresented groups in health research will, in the long run, enhance the quality of that research.
5. Agency heads, including the NIH Director, should have discretionary authority to respond quickly (with funds and personnel) to unanticipated research needs or opportunities.
6. The need for clinical research should be reaffirmed, both as a way of testing new therapies and as a method for evaluating existing "standard and accepted" therapies.
7. The importance of investigator-initiated research proposals should be acknowledged; however, a role should also be accorded to agency-initiated health research.

Two comments on the interrelationship among these prerequisites may be in order. First, there were differences of opinion within the Panel on the extent to which research should be targeted or health-problem-oriented.

However, there was strong support for the notion that the agencies can and should perform a "matchmaking" function, bringing into contact investigators whose research could be mutually illuminating and supportive and thereby enhancing the impact of the research on the development of new knowledge and on the solution of national health problems.

Second, in one and one-half days the Panel was unable to reach definitive conclusions on the question of priority-setting. However, several potentially helpful suggestions emerged from the Panel's deliberations. It was agreed that as a factual matter priority-setting within a clearly defined area of health research is less difficult than priority-setting among widely divergent areas or types of research. The Panel considered the notion of keying at least some types of research to the burden of illness as determined by various measures, e.g., morbidity, mortality, or years of expected life lost. However, some Panel members objected that research opportunity should be taken into account in addition to burden of illness; that is, unless potentially fruitful research hypotheses have been formulated, money allocated to a burdensome illness is not likely to be well spent. On the level of macroallocation, two suggestions emerged from the Panel: (1) the health research budget should perhaps be correlated in some way with the annual national or Federal expenditure for health care; and (2) as noted above, members of the public should perhaps be consulted to ascertain their views on the most important health-research priorities.

V. The Evolving Ethical and Legal Context for Health Research

The primary aim of the Panel in including this topic in the present report is to signal an important aspect of health research which was, for the most part, ignored by the President's Biomedical Research Panel. The DHEW Draft Health Research Principles devotes significant attention to this issue in a paragraph which includes the following sentence:

Research processes, guided by ethical considerations, must assure the protection of the rights and well-being of research subjects -- both human and animals -- and the health and welfare of laboratory workers, the public, and the environment. 7/

The Panel did not have sufficient time to develop a detailed analysis of this ethical and legal context for health research. It merely noted, as a matter of fact, that review procedures have been developed within the past twenty years for Federally funded human research and for Federally funded recombinant DNA research. Members of the Panel also observed that even nonregulatory agencies within DHEW have become involved in the setting of ethical and procedural standards which are then implemented primarily at the local level.

Members of the Panel on Unifying Concepts affirmed the importance of ethical and legal considerations in the conduct of health research. They expressed the hope that an appropriate balance can be struck between the promotion of health research, on the one hand, and the protection of subjects, the public, and the environment, on the other.

VI. Appropriate Roles for the Various DHEW Agencies in Health Research

The Panel on Unifying Concepts had insufficient time to discuss this issue in detail. In addition, the non-Federal members of the Panel generally lacked the intimate knowledge of the various DHEW agencies' missions and programs which would be required to render an informed judgment on the issue.

The Panel's primary general concern was that there be a careful coordination of scope and mission among the various DHEW agencies involved in health research. The Panel also encourages the development of more effective mechanisms for communication of health research opportunities and results among the various DHEW agencies.

VII. Relationship of DHEW Agencies to Other Groups Interested in Health Research

Again, on this point the Panel can make only brief, general recommendations. Coordination among Federal agencies in health research is highly desirable. Interagency cooperation has already occurred in the setting of ethical and procedural standards for both human research and recombinant DNA research. Similar consultation on health research opportunities and programs already is practiced between DHEW and non-DHEW agencies; such consultation should be expanded in the future.

In some types of health research--for example, epidemiological research--extensive cooperation currently occurs between DHEW agencies and State and local health departments. The possibility of extending this type of coordination to additional areas of health research should be explored.

The relationship of DHEW agencies to the private sector in health research is a multi-faceted question. One DHEW agency, the Food and Drug Administration, has had a long-standing regulatory relationship to manufacturers of certain products of health research. More recently, departmental policies have been developed for the patenting and licensing of health-related inventions produced with the assistance of DHEW health research support. The primary aim of these policies has been to facilitate the rapid transfer of health technologies from the laboratory to the marketplace. Currently, DHEW faces the question of whether to accept private industry's request for a set of standards and a review procedure for recombinant DNA research conducted in the private sector. In the limited time available to it, the Panel was unable to develop general recommendations for the relationship of DHEW to the private sector in health research. One specific recommendation advanced by several witnesses and Panel members was that DHEW agencies supporting health research develop matching-grant programs, in which contributions of private foundations toward designated health research areas or projects would be matched by Federal support.

Finally, one Panel member urged that DHEW not confine its health research focus to the American setting but consider, as well, the international burden of illness. This broadened perspective would encourage international cooperation in research and a particular concern for research directed toward the conquest of the infectious diseases which still bedevil many citizens of our world.

VIII. Summary

In summary, the major health research principles supported by most or all members of the Panel on Unifying Concepts are the following:

1. Fundamental research should be construed broadly to include the molecular, cellular, organismic, and population levels.
2. The Federal Government should support health research, and the rationale for such support should be clearly presented to the public which makes such support possible.
3. The decision-making process in the formulation of health research policy should be both open and accountable.
4. The funding and training of young investigators are essential to the future of health research.
5. There should be long-term stability in the funding of health research, but within this stability of funding, there should be sufficient flexibility to allow for a rapid response to promising new research opportunities.
6. The need for a science base (or basic research) should be reaffirmed.
7. A tension may exist between the quest for excellence and the concern for democratization in health research. Efforts to involve previously underrepresented groups in health research should be continued.
8. DHEW agencies can perform an important matchmaking function by identifying mutually relevant and reinforcing research efforts.
9. The setting of health research priorities among various fields and approaches remains one of the most difficult problems in health research.
10. Health research policies should be formulated in the light of a gradually evolving set of ethical and legal standards for the conduct of such research.

Footnotes

1. U.S., President's Biomedical Research Panel, Report (9 vols.; Washington, D.C.: U.S. Department of Health, Education, and Welfare, April 30, 1976).
2. Preamble to the Constitution of the World Health Organization, Official Records of the World Health Organization 2, p. 100.
3. U.S., President's Biomedical Research Panel, Report, p. 7.
4. "Draft Department of Health, Education, and Welfare Health Research Principles," p. 18.

5. Ibid., p. 21.

6. Ibid., p. 20.

SECTION B

National Conference on Health Research Principles

The National Conference on Health Research Principles, held at the National Institutes of Health on October 3-4, 1978, was designed to serve both as a forum to elicit additional public advice and to reach consensus on the health research principles the Department should adopt. This Section contains the Conference program, opening remarks made at the plenary session the morning of the first day of the Conference, and a list of the public witnesses who provided oral testimony before each of the five Conference Panels. (Copies of the public testimony are contained in Appendix C.)

NATIONAL CONFERENCE ON
HEALTH RESEARCH PRINCIPLES

October 3-4, 1978
National Institutes of Health
Bethesda, Maryland

PROGRAM

Tuesday, October 3

8:30 - 9:00 a.m.: REGISTRATION

Building 10 (Clinical Center), First Floor,
Corridor Entrance and Lobby Adjacent to
Masur Auditorium

9:00 - 9:45 a.m.: OPENING PLENARY SESSION

Building 10, Masur Auditorium

• Opening Remarks:

- The Honorable Joseph A. Califano, Jr.,
Secretary of Health, Education, and Welfare
- Dr. Julius B. Richmond, Assistant Secretary
for Health, Department of Health, Education,
and Welfare
- Dr. Donald S. Fredrickson, Director, National
Institutes of Health and Conference Chairperson

10:15 a.m. - 12:15 p.m.: PANEL SESSIONS

Public Testimony by Pre-Registered Witnesses

• PANEL 1 - FUNDAMENTAL RESEARCH

Chairperson: Dr. Donald W. Seldin
Professor and Chairman
Department of Medicine
Southwestern Medical School
University of Texas

Co-Chairpersons: Dr. Robert Berliner
Dean, School of Medicine
Yale University

Dr. Mildred Cohn
Professor, Department of
Biochemistry and Biophysics
University of Pennsylvania

Dr. Cyrus Levinthal
Professor, Department of
Biological Science
Columbia University

Executive

Secretaries: Dr. Vida Beaven
Special Assistant to the
Deputy Director, NIH

Dr. Michael Ebert
Chief, Section on
Experimental Therapeutics
National Institute of Mental
Health Intramural
Research Program, ADAMHA

Dr. Carl Leventhal
Deputy Director
National Institute of
Arthritis, Metabolism and
Digestive Diseases, NIH

Dr. Marvin Snyder
Special Assistant to the
Deputy Director
Division of Research
National Institute on
Drug Abuse, ADAMHA

Session A - Conference Room 6, Building 31,
C Wing, 6th Floor

(Dr. Seldin and Dr. Levinthal;
Dr. Beaven and Dr. Snyder)

Session B - Conference Room 7, Building 31,
C Wing, 6th Floor

(Dr. Berliner and Dr. Cohn;
Dr. Leventhal and Dr. Ebert)

● PANEL 2 - CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH

Chairperson: Dr. Paul Marks
Vice President for Health
Sciences
College of Physicians and
Surgeons
Columbia University

Co-Chairpersons: Dr. Barbara C. Hansen
Associate Dean for Graduate
Studies and Research
School of Nursing
University of Michigan

Dr. Samuel O. Thier
Professor and Chairman
Department of Internal Medicine
School of Medicine
Yale University

Dr. P. Roy Vagelos
President
Merck Sharp & Dohme Research
Laboratories Division
Merck & Company, Inc.

Executive

Secretaries: Dr. Samuel Korper
Senior Research Manager, GMENAC
Office of the Assistant
Secretary for Health

Dr. Ira Raskin
Director, Office of Program
Development
National Center for Health
Services Research

Dr. Robert Ringler
Deputy Director
National Institute on Aging
National Institutes of Health

Dr. Frank Sullivan
Executive Director
National Institute of Mental
Health Research Advisory
Group, ADAMHA

Session A - Conference Room 10, Building 31,
C Wing, 6th Floor

(Dr. Marks and Dr. Vagelos;
Dr. Korper and Dr. Ringler)

Session B - Conference Room 8, Building 31,
C Wing, 6th Floor

(Dr. Thier and Dr. Hansen;
Dr. Raskin and Dr. Sullivan)

● PANEL 3 - HEALTH REGULATION AND PROMOTION

Chairperson: Dr. Leon Eisenberg
Presley Professor of Psychiatry
Harvard Medical School and
Senior Associate in Psychiatry
Children's Hospital Medical
Center

Co-Chairperson: Dr. Denise Kandel
Department of Psychiatry and
School of Public Health
Columbia University and
New York State Psychiatric
Institute

Executive
Secretaries: Mr. Robert Frankel
Deputy Associate Director
for New Drug Evaluation
Bureau of Drugs, FDA

Dr. William Gay
Director, Extramural
Activities Program
National Institute of Allergy
and Infectious Diseases, NIH

Location Conference Room 4, Building 31,
A Wing, 1st Floor

● PANEL 4 - RESEARCH CAPABILITY

Chairperson: Dr. William H. Danforth
Chancellor
Washington University

Co-Chairperson: Dr. Elizabeth Shull Russell
Senior Staff Scientist
Jackson Laboratory

Executive

Secretaries: Dr. Doris Merritt
Special Assistant to the
Director, NIH

Dr. Jay Moskowitz
Director, Office of Program
Planning and Evaluation
National Heart, Lung, and
Blood Institute, NIH

Location Building 10, Clinical Center,
14th Floor

● PANEL 5 - UNIFYING CONCEPTS

Chairperson: Dr. Lewis Thomas
President
Memorial Sloan-Kettering
Cancer Center

Co-Chairperson: Dr. John A. Gronvall
Dean, Medical School
University of Michigan

Executive

Secretaries: Dr. Paul Parkman
Deputy Director
Bureau of Biologics, FDA

Dr. Seymour Perry
Associate Director for Medical
Applications of Research, NIH

Location Building 1, Wilson Hall, 3rd Floor

12:15 - 1:45 p.m.: LUNCH

1:45 - 5:15 p.m.: PANEL SESSIONS

Continuation of Public Testimony (Same Locations)

(Coffee Break: 3:00 - 3:15 p.m.)

5:15 - 6:45 p.m.: DINNER

6:45 - 10:30 p.m.: PANEL WORKING SESSIONS

Development and Revision of Draft Reports

(NOTE: After a short period of time to summarize, the two split panels will reconvene as single, full Panels at the following locations -- Panel 1, Fundamental Research, Conference Room 6, Building 31, C Wing; and Panel 2, Clinical Applications and Health Services Research, Conference Room 10, Building 31, C Wing.)

Wednesday, October 4

9:00 a.m. - 12:30 p.m.: PANEL WORKING SESSIONS

Review and Revision of Draft Reports

(Same Locations; No Split Panels)

(Coffee Break: 10:30 - 10:45 a.m.)

12:30 - 2:00 p.m.: LUNCH

2:15 - 4:00 p.m.: CLOSING PLENARY SESSION

Building 10, Masur Auditorium

- Summary of Draft Panel Reports by Panel Chairpersons
- Closing Remarks - Dr. Donald S. Fredrickson
Director
National Institutes of Health
and Conference Chairperson

NATIONAL CONFERENCE ON
HEALTH RESEARCH PRINCIPLES

Opening Remarks By

Joseph A. Califano, Jr.
Secretary of Health Education, and Welfare

Dr. Julius B. Richmond, Assistant Secretary for Health
Department of Health, Education, and Welfare

Dr. Donald S. Fredrickson, Director
National Institutes of Health and
Conference Chairman

October 3 and 4, 1978
National Institutes of Health
Bethesda, Maryland

OPENING REMARKS

Dr. Fredrickson: We're extremely pleased this morning to begin this important two day exercise with comments from the Secretary of Health, Education, and Welfare. And it's my great pleasure to introduce to you, Mr. Joseph A. Califano, Jr. Mr. Secretary?

Secretary Califano: I am very pleased to be here this morning, to open this Conference. I have little to contribute to your deliberations intellectually or as scientists and experts in biomedical research. I would like to give you a sense of what I hope can be achieved over the long run and what I hope will begin here.

I suspect that none of you are strangers to this setting, or to one another, or to conferences generally. But I think that this Conference, among many that you have attended, may well be the beginning of something that we can all look back upon as historic.

I want to thank each of you personally because I know many of you have made sacrifices and have given up your own personal convenience to be here for these two days, and to be a part of this process. I hope you'll accept my special thanks for coming and for the contribution I know you will all make.

I'd like to say something about the importance of the meeting and to sketch out for you roughly the timetable over which we would like to develop a five year strategy and budget for HEW's health research, and to sketch the role that I hope this Conference will play.

The Department of HEW, the largest in the government, has many missions, but not one of them is more important than the one that brings you here today, the mission of research. And nothing could be more important to the future of our research efforts than this meeting and the process it begins, for what you begin here today will help determine how we and others will apportion our research support over the next five years.

As you know, I raised the issue of the future of health research and federal support before the annual meeting of the American Federation for Clinical Research, last spring. I suggested then that the government and the research community should embark jointly upon an important process, the development of a multi-year research strategy to guide the allocation of limited government health research dollars. For even as President Carter moves to strengthen our national commitment to basic research, and hopefully to improve

our nation's research capacity, we simply cannot ignore the reality of the limits of our resources. Limits on the amount of basic research that the Federal government can afford to finance, limits on the ability of research to help with some of the truly enormous health problems facing the nation. Limits that will be with us, with you and with me, for the foreseeable future.

And as I said in San Francisco, in an era in which resources are limited, we must develop a better, more thoughtful, more intelligent strategy to guide the allocations of Federal research dollars. A multi-year plan covering at least five years will serve to level out the annual appropriation fluctuations that make rational research planning so difficult.

I recognize that there's no way in the world of research that we can dot every i and cross every t, and that what's discovered tomorrow that none of us thought was there will have an enormous impact at various points on what happens to our dollars in the research area. And I recognize, therefore, that flexibility is necessary at all times. But I do want to emphasize four important benefits that I see from developing a multi-year strategy.

First, such a strategy can help us all, especially those of us in government, resist some of the inevitable but not always desirable pressures that attend the distribution of substantial research dollars. You're all familiar with the kind of disease-of-the-month pressure that attends the budget process within HEW and within the Congress.

Second, such a strategy can point directions that extend over a more extended and stable period than next year's budget cycle.

And third, such a strategy should emphasize the relationship between health research and unmet health needs, and thus I hope, may stimulate a creative interchange among the nation's laboratories, the health care delivery system, and the regulatory process.

And fourth, such a strategy should help us organize our research efforts so that they will bear some recognizable relationship to the nation's health needs.

If we are to benefit from the development of a five year strategy or any sort of strategy, it must be as specific as possible. It must face up honestly and candidly to hard choices. Indeed, it must seek out and highlight those choices, not paper them over. To be useful, the plan cannot simply endorse generalized statements in support of research. To the extent possible it must provide guideposts to indicate the type of research that should be supported. It must indicate the direction in which federal support for research should proceed.

Therefore, I would like to set a very specific goal and challenge before the Conference and to urge that you keep this goal and this challenge in mind over the next two days and thereafter, as you review and comment on the papers and principles that come from this Conference.

By the Fall of 1979, I have asked that a full scale five-year health research budget be developed, a budget that attempts to speak out by agency and by general type of research the funding targets for research for the fiscal years 1982 through 1987. That budget then of course could be rolled over and changed each year, but we would always be looking five years out once we get through this fundamental and basic process that you begin here today.

As I emphasized in San Francisco, I recognize that the process -- the process by which we arrive at any five-year strategy is almost as important as the strategy itself. We intend to conduct this process with the fullest participation by the affected communities and by the public. We intend to seek the advice and counsel from all quarters at every stage of the process, from the health research community, from the health care community and the medical profession, from the public, and of course from the members of the Congress.

We have already begun this consultation process in earnest, as most of you realize. In preparation for this Conference, I wrote hundreds of individuals and organizations, seeking suggested principles and seeking their advice on the preparation of a health research strategy. In addition, individual agencies within HEW have canvassed their own constituencies extensively, seeking comments and suggestions. I also sought comments and suggestions from all other government departments whose work is related to HEW's research or on whom our research impinges.

This National Conference represents the most important opportunity at the very start of the process, at the very beginning, for public debate and discussion, but we will seek comment and try to stimulate public debate at every step, as we develop our research strategy and our budget.

To meet this goal will require hard work. Don Fredrickson has suggested, and I agree, that the development of a five-year health research budget should be done in three stages. First, the basic principles.

Based on this Conference and on work that will follow close on its heels, we should adopt by early 1979 a set of basic principles that would underlie a five-year research plan. The principles should set out the fundamental tenets of our research strategy, identifying the most important scientific and ethical considerations on which a research strategy should be based, as well as identifying potential criteria for choosing among various research priorities. Each of you attending this Conference has received a set of draft principles that were developed from suggestions made by HEW agencies and from literally hundreds of public comments. The Conference panels will refine and perhaps thoroughly rewrite these draft principles. That's what you're here for. Based on the work of this Conference, we intend to publish, sometime by the end of November, a tentative statement of principles. We will publish final principles early in 1979, only after carefully revising the principles in light of all the public comments we receive and the comments we receive from you as individuals upon the panels' work, and in light of an intensive critique which we have asked the Institute of Medicine to conduct and which the Institute has agreed to conduct.

The research goals is the second phase. During 1979, we will attempt to spell out specific research goals, based upon the principles finally adopted. The goals might very well address the specific research missions of present health agencies and would be intended to establish specific priorities and set specific policies for HEW's research agenda in health, and for the commitment of HEW's research dollars in this area.

During 1979, we will develop these goals by again seeking advice, publishing tentative goals, and then soliciting additional comments and criticisms, with mid-1979 as our date, our target date, for completion.

Once specific health research goals have been identified, we will seek to translate them into a concrete five-year budget which we will publish in the Fall of 1979, so that at that point in time you will know exactly what our thinking is for the next five years, and you will have a chance to comment on it as we go through our budget process thereafter, and you will have a chance, not when the budget is up on the Hill, for one year, to comment through the appropriations process only, but also to look at it, examine it, over a longer range.

We, of course, must by the nature of the Federal budget cycle, begin functioning and operating on the basis of that budget, but we will not do so inflexibly.

As you review the draft principles you have received, and as you read over the summary of the public comments we have received so far, and as you listen to the panel discussions, I hope that you will focus on the hard questions, the questions of priority and of choice for which there are no easy answers. The questions on which understanding and perhaps consensus will develop at best only after long hours of debate and discussion.

Every one of us here is committed to long-term support for basic research. Every one of us believes in research to solve today's immediate and pressing health problems, but we must make choices. It is a hard fact but a reality that not every area of basic research, perhaps not even every promising one, can be explored at once or with equal energy and equal commitment of resources.

Similarly, as we move toward the applied research end of the spectrum we must also be selective. We cannot do everything at once. Neither can we only propose new or greatly expanded initiatives requiring large increases in federal support. Rather, we must first make the best use of what we now have on hand, and to do this we will have to choose wisely and with foresight, and it is here that, more than any other place, we need all the help we can get from you.

So we look forward to seeing and using the principles that emerge from this Conference. I would like to thank you all again, the scientists and health professionals so eminent here on the stage, who provide leadership as chairpersons and co-chairpersons of the Conference, of the panels of the Conference. The diverse range of people, you who have agreed to serve on these panels, who represent almost every kind of institution and background and expertise and intellectual achievement. Don Fredrickson and his staff who have done so much so far. Dr. Richmond and I have dragooned Dr. Fredrickson into heading this effort, into supervising and coordinating the writing of the draft principles, and generally overseeing the development of a department-wide health research strategy. A role that for any other NIH Director might carry considerable discomfort, but I know of nobody with a finer, broader scope, of no one who has been fairer in the judgments he's made and the advice he's given to me, of no one who has been more sensitive to opening up the process to the public and to the experts outside of government, of what we do in government in the research area, than Don Fredrickson. I think his work in the DNA, recombinant DNA guidelines, is a testament to the fact that government can operate publicly, that it is important for government to operate publicly in the scientific area, that while not every individual citizen in this country can understand the kind of considerations and can understand

with the kind of sophistication the considerations that go into the judgments and recommendations and arguments that you will make and do make, we can all as a nation at least permit our people to bear witness to the debate and the dialogue, and I think Don, more than anyone else in the scientific community, has contributed to that. So I'm particularly grateful to him for taking on this task, a task he does not need in addition to all his duties as head of NIH.

As for me, I look forward to working with you, to giving whatever skills I have in the public policy arena or the political arena, to strengthening our nation's health research program, of which in biomedical research what we do here at HEW is such a significant part. It is, I guess, something above 60 percent of the dollars in biomedical research that now come from HEW, and a large proportion of dollars that follow those of ours, and it is important that we spend them with a great deal of intelligent -- intelligence and foresight.

When I first became Secretary, I came out here to NIH and I said that I would do my best to take the politics out of research in this country. The symbol of that at that particular occasion, 20 months ago, was to announce the continuing appointment and reappointment by the President and myself of Dr. Fredrickson. I have tried to do that in every appointment that I have made in this area, beginning with Dr. Richmond and then with all the other appointments in the health area that Julie and I have labored over so intensively. We have, for most jobs, interviewed scores of people. We have introduced into the FDA -- Don Kennedy has a system whereby search committees are formed to try and attract the best that we can, to be bureau chiefs. We've tried to put the best people in all of these jobs, in all of these health jobs, all of these research jobs, without regard to politics. The next -- that's one of the most, if not the most important things, that someone like me can do in this area. I think this five-year plan is the next most important thing. If you -- and I know it won't be easy; I know it will be difficult, and a lot of you won't benefit five years out from what you do here today but if we can put together a plan, however tentative it turns out to be, that can be a lighthouse, a guidepost, for the Congress, for the Department, for others, over a five-year period, that can provide a sense of stability to the work that you and your colleagues do that is so important to the health and well being and development, and even freedom, of this country. If we can do that, if you can help us do that, you will have made such a single contribution and single achievement in terms of putting this research process on the highest plane we can put it on, on the most effective plane we can put it on. We can never separate it, of course, from the politics and desires and aspirations of human need, from the health problems of our people, and we shouldn't. But we should be able to make it a much longer run process, a much more stable process, and thus a process that will better serve the citizens of this country and all mankind. Thank you.

Dr. Fredrickson:

Mr. Secretary, I know that you have to leave this arena for another one. Before you go, I want to thank you very much on behalf of everyone at this Conference, for by your remarks you have made clear that your intent in conceiving of this meeting and its purpose was a real one. I should like to speak for the panelists and the participants in telling you that we accept your challenge to attempt to do this and prove that it is a realistic one. We are very grateful indeed that you have started us off, and we shall attempt to carry out your difficult, but hardly uninteresting challenge. Thank you, Mr. Secretary.

Ladies and gentlemen, let me introduce the persons who are on the platform. Many of you have recognized them, but those of you who are on the Panels and particularly those who will be witnesses before them today should have the benefit of knowing exactly who they are. We have arranged the chairpersons and co-chairpersons of the five Panels or foci in the following order:

On my extreme right are the chairpersons and co-chairpersons for the Panel on Fundamental Research. It is indicative of the response you have made, that that Panel has had to be split into two parts--at least for the purpose of hearing testimony today. On the far right are Dr. Donald Seldin, Dr. Robert Berliner, Dr. Mildred Cohn and Dr. Cyrus Levinthal. Panel two on Clinical Applications and Health Services Research is also split into two parts and is chaired and co-chaired by Dr. Paul Marks, Dr. Barbara Hansen, Dr. Sam Thier and Dr. Roy Vagelos. Panel three, dealing with Health Regulation and Promotion, is chaired and co-chaired by Leon Eisenberg and Denise Kandel. Panel four on Research Capability is chaired and co-chaired by Dr. William Danforth and Dr. Elizabeth Russell. We regret very much that the intended chairman of Panel five on Unifying Concepts, Dr. Lewis Thomas, has had an injury from which he is recovering, and he could not be here today. His place as chairman will be taken by Dr. John Gronvall. And next to him is Dr. LeRoy Walters from the Panel, who has offered to serve as co-chairperson.

And now, ladies and gentlemen, it is a pleasure for me to introduce again to you a person already mentioned this morning, who is central to the management, the administration and the guidance of health research in this country and in this Department. It is a pleasure to have Dr. Julius Richmond, the Assistant Secretary for Health, and also the Surgeon General with us today. Dr. Richmond.

Dr. Richmond:

Thank you very much, Don. I'd like to extend, on behalf of the entire Public Health Service, our appreciation to all of you for coming; and in the process, also extend our appreciation to those of you who have done so much to bring this Conference to this point, and particularly to Don Fredrickson and his staff, the staff of other agencies and the Department, who have worked very hard preparing for the Conference and providing you with the documents which you have received.

From what you have heard, I think you will agree that we have gained the Secretary's attention to research. And it is his attention, our collective attention, and certainly the attention of people throughout the nation, to our research enterprise in this nation which brings us all together on this occasion.

The development of principles is a complex task with potential long range impact, as the Secretary has already indicated, on the establishment of research priorities. These principles and priorities will affect our knowledge base, and consequently, the state of health services and the health status of the nation in the future. In considering the process that we are setting in motion, I have thought many times about the immense number of distinctly different views that can be brought to bear on the subjects before the panels established for this Conference. Some of the principles that will be developed, although important in and of themselves, may conflict with other principles, and choices will have to be made in terms of the weight of each one.

One of the hallmarks of progress is the rapidly increasing scope and depth of knowledge. As our knowledge of natural processes increases, as the number of unnatural chemical and physical elements in our environment increases, and as the health delivery systems grow more complex, we are led inevitably to further subdivide our research, regulatory and care efforts in order to maintain the expert knowledge necessary to attack our health problems. From this you may judge that maintaining oversight of the increasingly diverse health fields grows more difficult by the year. To counter these difficulties, as the Secretary has indicated, we have invoked a time-honored and successful practice which has often been employed in this Department -- to draw in expert outside advice to add collective wisdom to the planning effort. The National Institutes of Health have certainly had a long tradition of consultation with extramural groups. It is for this reason that I am always bemused when we are asked what our policies are. We like to think that they reflect your aspirations and the aspirations of people throughout the country.

The process of development of principles on which we are now launched is, of course, a classical example of this approach. Because the end product of this several stage process--that is, a five year health research strategy to include biomedical, behavioral and health services research for the Department--may be expected eventually to impact on all health missions of the Department, and upon innumerable interests and concerns of the national health research community, we have solicited advice from virtually every type of medical and health professional specialty. We are convinced of the importance of giving this planning effort the broadest possible base, in the form of a set of agreed-upon health research principles which have been fully discussed and selected with all of the collective wisdom we possess.

In our efforts to reap the greatest benefits from Departmental research activities, we will discover many research needs within our own agencies. Since the health research activities are largely concentrated within four agencies in the Department, some of the other agencies with health missions may have difficulty assembling the necessary knowledge base for administering their health care, prevention, and regulatory programs. As an example, in environmental toxicology, health problems are becoming apparent at a steadily increasing rate, and each regulatory policy decision must be preceded by the assembling of a firm base of scientific knowledge. In a similar manner, agencies which administer health care programs may recognize problems of health care practice or excessive health care costs which may be attacked through definable research projects. We must seek means of increasing the interactions between the various agencies that can use the results of research in fulfilling their needs, and the agencies that provide the expertise to address those needs. We must also look outward from the Department with increased attentiveness in defining our research goals. The tools of epidemiology, demography, and health statistics on the incidences and prevalence of illness and problems should be refined and used more carefully in choosing our research goals.

The necessity, as the Secretary indicated, of a stable basic research effort is well recognized. But the funds for developmental and applied research may be more carefully focused upon the most pressing problems in disease prevention, health care, and other practical public health areas through the process of which you are a part. I'm sure this Conference will succeed in this planning effort, and that we will enhance the Department's use of our nation's excellent history and tradition in developing health research resources.

Just one final word concerning recent history. During the halcyon days of the fifties and sixties, we did not need, perhaps, to plan so

explicitly. The abundance of resources did not require it. In more recent years, there have been some pressures to apply constraints. Public interest has increased and greater accountability, whatever that may be, is being asked for. It becomes necessary, therefore, for us to recommit ourselves to the search for new knowledge through research. This necessitates, however, our having a strategy and making it explicit.

Once again, I thank you in advance for your efforts in this Conference and I look forward to examining, with Don Fredrickson and with Secretary Califano, the forthcoming principles which you will be generating. Thank you.

Dr. Fredrickson

Thank you, Dr. Richmond.

You have received the agenda and format for this Conference in the materials that were mailed to you prior to your arrival here, or given to you upon your coming this morning. The overall intent - the renewal of the expression that "this is a game which is being played for keeps" - you have heard already from the Secretary and from the Assistant Secretary for Health.

I think my task now is primarily to point out some logistical features that we hope will make this meeting work smoothly and effectively. Before I do, though, I would like to make one or two comments. Last Tuesday evening, I was in Rome at the Villa Taverna, which is the beautiful American Embassy there, as a guest of the Ambassador and Mrs. Gardner. Twenty Italians, a scientist from the National Research Council of Italy, some from the Ministry of Health, and other areas engaged in a long debate about some dramatic proposals before the Italian legislature which refer to health, to science and to the universities. In those proposals and in the tensions that they produced, one can see the whole microcosm of what we are talking about here today and tomorrow, displayed in terribly stark terms. This is a nation about to convert to a national health service, full of urgent problems that will have to be solved; a desperate need for new information, knowledge and wisdom in coping with those problems; an intent perhaps to change the manner in which scientific funds are distributed in that country; and also an intent to alter the structure of the universities.

Then I traveled to London to attend a meeting of the European Medical Research Council, and sitting in the tiny room in the Royal Society were the heads of institutions and organizations that must fund about three quarters of the world's biomedical research, and replayed again were those very same problems. The problems are paradoxically created by an exuberant opportunity for continued discovery in biology and medicine, confronted by those same urgent practical problems that demand solution; questions of the relationship of the government to the universities, how to structure, how to create stability, how to manage to cope with these problems in the midst of such opportunity.

This Conference I suppose, as conceived by the Secretary, is kind of a peculiarly American address of these very same problems. We are here to try to succeed in a public way by lengthy discussions with a

serious intent, to see how we can grapple with these many problems and to effect some plans, with some hope for an organized and better-structured approach to their solution. Some of this work will require reaffirmation of old principles; perhaps it will involve introduction of new ones.

The Department is extremely fortunate to have acquired your services, as members of the Panel -- with an astoundingly good group of chairpersons and co-chairpersons to guide us through these next couple of days -- and as witnesses, showing a great deal of interest and willingness to participate. We structured this Conference to permit maximum comment and advice from the whole spectrum of people who may be interested in the subject, through written remarks as well as public testimony. All of you have chosen the Panels toward which you will address your remarks, and sometimes your presentations will overlap. If you are on the Panels, keep this potential for overlap in mind as you direct your attention to drafting the principles that will emerge from your exercises today and tomorrow.

We have assembled a great deal of staff support for you. Every person who testifies is to have written comments and those are going not only to be distributed to the Panels forthwith, but also to be summarized for the Panels, to save them time.

There will be a good deal of organized support for each of the Panels, in order to accomplish the hearing of testimony from a very large number of people within an extremely short time. I know it is ridiculous to ask you to testify in five minutes, but that is all the time we can allow, due to the vigorous response to the invitations for this Conference. Remember that what you have to say will be available in complete form to the Panel; you should stress those key points that you want to be sure are considered. If the Panels have time, I am sure they would like to discuss these points with you, but their time is extremely limited. If time constraints make it necessary for the chairperson to request that you yield the floor before you have completed your remarks, do keep in mind that the Panel will have a copy of your full text.

At each Panel location there are ten seats reserved for persons who are registered as witnesses. You have received testimony schedules which identify when you are expected to testify. The receptionist at each of the Panel sites will maintain the schedule, and will monitor the flow of witnesses. Please identify yourself as you arrive at the Panel site, whether or not you find room inside. In order to allow witnesses a sufficient opportunity to become oriented to the proceedings, we ask that only persons who have not yet testified and who are next on the schedule occupy the section reserved for witnesses. Following testimony, each witness is then requested to find other seating in the room.

I would like to call the attention of the members of the Fundamental Research Panel and the Clinical Applications and Health Services Research Panel to the roster included in this morning's registration materials. A number of changes have been made from the previous roster in the division of Panel members between the two locations for each of those Panels. Please check again the location which you are to attend.

Other than the seating that I have mentioned for witnesses, and naturally for the Panel members themselves, reserved seating at the Panel sites has been arranged for only a small number of people who have key roles in this planning process. All other persons who are pre-registered and are wearing a Conference badge will be admitted to general seating at any of the Panel sites, as space permits. All working Panel sessions as well as the testimony sessions will be open to you.

Today is the second day of Rosh Hashanah. For that reason, one or two Panel members will be joining their Panels tomorrow, and time has been set aside tomorrow morning to receive testimony from any witnesses who are observing the holiday today.

After the Conference, the public record will remain open for two weeks so that any participants or other persons wanting to make further comments may do so before preparation of the final draft of the principles. The Panel reports which the chairpersons will deliver tomorrow at the second plenary session beginning at 2:00 p.m. will not be released in written form at that time. The chairpersons will be given two more weeks of additional time to refine the reports before their release for public comment.

As you have already heard, during November the last draft of the consolidated Panel reports will be sent to all persons who participated in the Conference, and public comments may again be submitted. The DHEW Steering Committee for this planning exercise will then consider the final report, and it will be presented to Secretary Califano for initiation of the actions that he described to you.

We will now adjourn to the Panel sites. Thank you very much for coming. We will see you again in the plenary session tomorrow afternoon.

NATIONAL CONFERENCE ON DHEW HEALTH RESEARCH PRINCIPLES

National Institutes of Health

October 3 and 4, 1978

RECORD OF TESTIMONY PROVIDED BY PUBLIC WITNESSES

PANEL 1: FUNDAMENTAL RESEARCH

Session A

- | | |
|---|--|
| 1. Dr. Richard A. Cooper | American Society for Clinical Investigation |
| 2. Dr. Houston Baker
Executive Officer | American Society for Pharmacology
Experimental Therapeutics |
| 3. Dr. Sue Thomas Hegyvary | Council of Nurse Researchers,
American Nurses Association |
| 4. Dr. Howard E. Morgan
Vice President for
Research | American Heart Association |
| 5. Dr. Richard B. Middleton
Associate Dean | New Jersey School of Osteopathic
Medicine |
| 6. Jerry M. Neal | Society of Teachers of Family
Medicine |
| | North American Primary Care
Research Group |
| 7. Dr. Lowell M. Greenbaum
Public Affairs Committee | Federation of American Societies
for Experimental Biology |
| Public Affairs Committee | American Society for Pharmacology
and Experimental Therapeutics |
| 8. Dr. Lester A. Mitscher | American Association of Colleges of
Pharmacy |
| 9. Dr. Robert P. Lowman
Scientific Affairs
Officer | American Psychological Association |
| 10. Dr. Thomas Roth
Chief Officer | Association for the Psycho-
physiological Study of Sleep |
| Executive Secretary-
Treasurer | Association of Sleep Disorders
Centers |
| 11. Dr. G. R. Noggle
Executive Officer | American Society of Plant
Physiologists |

PANEL 1: FUNDAMENTAL RESEARCH

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|---|---|
| 12. Dr. Robert M. Bock | American Society of Biologists
and Chemists |
| 13. Col. Robert E. Glasgow
President | Down's Syndrome Congress |
| 14. Dr. Joe W. Grisham
Chairman, Research
Committee | Association of Pathology Chairmen |
| 15. Dr. John I. Nurnberger
Professor | Indiana University Medical Center |
| 16. Dr. Howard J. Brinkley
Washington Representation | Society for the Study of
Reproduction |
| 17. Elmer Cerin
Area Vice President | Amyotrophic Lateral Sclerosis
Society of America |

Session B

- | | |
|---|--|
| 1. Dr. Frank G. Standaert | American Society for Pharmacology
and Experimental Therapeutics |
| 2. Dr. Harlyn O. Halvorson
Past President | American Society for Microbiology |
| | Association of American Medical
Colleges |
| 3. Dr. William R. Cunnick
President | American Social Health Association |
| 4. Joyce Pennington
Secretary, Bureau
of Research | American Osteopathic Association |
| 5. Margarita C. Trevino
President | Latino Caucus
American Public Health Association |

PANEL 1: FUNDAMENTAL RESEARCH

- | | |
|---|--|
| 6. Dr. Everett R. Rhoades
Board Member | Association of American Indian
Physicians |
| 7. Dr. Phillip P. Cohen | American Society of Biological
Chemists |
| 8. Dr. William F. Collins, Jr.
Secretary | Society of Neurological Surgeons |
| 9. Dr. Charles F. Ehret | International Society for
Chronobiology |
| 10. Dr. Edward G. High
Professor and Chairman | Department of Biochemistry and
Meharry Medical College |
| 11. Dr. Mahlon B. Hoagland | Delegation for Basic Biomedical
Research |
| 12. Dr. Federico Welsch
Governmental Affairs
Liaison | Association of Independent Research
Institutes |
| 13. Dr. Richard L. Pharo
Assistant to the
President for Science | Eye Research Institute |
| 14. Dr. William R. Barclay
G.V.P. for Scientific
Publications | American Medical Association |
| 15. Dr. Ernst Knobil
President-Elect | American Physiological Society |
| 16. Dr. John C. Partin
Program Director | Clinical Research Center,
Cincinnati Children's Hospital
Research Foundation |

PANEL 2
CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH

SESSION A

- | | |
|---|--|
| 1. Dr. Thomas C. Chalmers
President
Dean | Mount Sinai Medical Center

Mount Sinai School of Medicine |
| 2. Dr. F. Owen Black
President | Association for Research in
Otolaryngology |
| 3. Dr. Barry Miller

Chairperson | State Mental Health Research
Directors Division
National Association of State
Mental Health Program Directors |
| 4. Joseph Hall
President | National Pharmaceutical Association |
| 5. Carrie Rogers
President | National Black Nurses Association |
| 6. Dr. Max E. Chilcote
Chairman, Committee
on Professional
Relations | American Association for Clinical
Chemistry |
| 7. Dr. Maurice Wood

Chairman | Society of Teachers of Family
Medicine
North American Primary Care
Research Group |
| 8. Dr. Thomas E. Morgan
Director, Division
of Biological
Research | Association of American Medical
Colleges |
| 9. Dr. A. Hollis Wolf
Chairman, Bureau of
Research | American Osteopathic Association |

PANEL 2
CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

SESSION A

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|--|---|
| 10. Dr. Kent W. Peterson
Executive Vice
President | American College of Preventive
Medicine |
| 11. Dr. Francis B. Palumbo | American Association of Colleges
of Pharmacy |
| 12. Eugene Michels
Associate Executive
Director of
Communications | American Physical Therapy
Association |
| 13. Dr. Merrill M. Mitler
Secretary-Treasurer | Association of Sleep Disorders
Centers |
| 14. Dr. Carol A. Lindeman | American Association of Colleges of
Nursing

Sigma Theta Tau, National Honor
Society of Nursing |
| 15. Dr. Henry H. Work
Deputy Medical
Director | American Psychiatric Association |
| 16. Dr. Robert M. Rice
Director, Policy
Analysis and
Development | Family Service Association of
America |
| 17. Dr. Maria New | Society of Program Directors of
Clinical Research Centers |
| 18. Dr. Robert L. Berg | Association of Teachers of
Preventive Medicine

American College of Preventive
Medicine |

PANEL 2
CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

SESSION A

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|--|---|
| 19. Dr. Tibor J. Greenwalt
Senior Scientific
Advisor | American Red Cross |
| 20. Dr. Frederick M. Parkins | American Academy of Pedodontics

American Society of Dentistry for
Children |
| 21. Dr. John Hein | American Association for Dental
Research |
| 22. Brita O'Carroll | Regional Emergency Medical Services
Program
North Central Texas Council of
Governments |
| 23. Dr. A. Everette James | Society of Chairmen of Academic
Radiology Departments |

SESSION B

- | | |
|--|---|
| 1. Dr. Burton E. Sobel | American Society for Clinical
Investigation |
| 2. Dr. Edward G. High
Professor and
Chairman | Department of Biochemistry and
Nutrition, Meharry Medical
College |
| 3. Dr. William F. Collins, Jr.
Secretary | Society of Neurological Surgeons |
| 4. Gloria Rookard
Manager, Patient
Services | Visiting Nurse Service of
Summit County |
| Secretary | National Black Nurses' Association |

PANEL 2
CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

SESSION B

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|---|--|
| 5. John W. Dieckman
President | National Reye's Syndrome Foundation |
| 6. Mary Lynn Porter
Director | Auburn Day Care Centers |
| 7. Dr. David W. Smith
Assistant Vice
President for
Health Services | University of Arizona at Tuscon |
| 8. Dr. Ida Marie Martinson | Commission on Nursing Research
American Nurses Association |
| 9. Dr. Esther Winterfeldt
President - Elect | American Dietetic Association |
| 10. Dr. Edward J. Sheridan | National Doctors for Life |
| 11. Sam Shapiro
Director | Health Services Research and
Development Center
Johns Hopkins Medical
Institutions |
| 12. Dr. Paul Sherlock
President | American Society for Gastro-
intestinal Endoscopy |
| 13. Barbara J. Syska
Research Analyst | National Right to Life Committee |
| 14. Thomas J. Byrne
Executive Director | Massachusetts Children's Cancer
Blood Program

Citizens Committee for the Conquest
of Cancer |
| 15. Dr. Leonard D. Fenninger
Vice President
for Education | American Medical Association |

PANEL 2
CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

SESSION B

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|--|---|
| 16. Dr. Jon B. Straumfjord, Jr. | College of American Pathologists |
| 17. Dr. Charles A. Walker | International Society for Chrono-
biology |
| 18. Dr. Evelyn V. Hess
Director | Arthritis Foundation Clinical
Research Center |
| 19. Dr. A. Kenneth Ciongoli | American Association of Colleges
of Osteopathic Medicine |
| 20. Dr. Ralph G. Robinson | American College of Radiology |
| 21. Dr. Gary R. Vanden Bos
Administrative
Officer, Mental
Health Policy | American Psychological Association |
| 22. Roma E. Brown | American Society for Medical
Technology |
| Acting Executive
Director | ASMT Education and Research Fund |
| 23. Elmer Cerin
Area Vice
President | Amyotrophic Lateral Sclerosis
Society of America |

PANEL 3
HEALTH REGULATION AND PROMOTION

- | | |
|--|---|
| 1. Thomas J. Byrne
Executive Director | Massachusetts Children's Cancer
Blood Program |
| 2. Eugene Michels
Associate Executive
Director of
Communications | American Physical Therapy
Association |
| 3. Dr. Richard L. Pharo
Assistant to the
President for Science | Eye Research Institute |
| 4. Dr. Jesse Roth
President - Elect | American Society for Clinical
Investigation |
| 5. Dr. Roy F. Goddard
President | Pediatric Pulmonary Association
of America |
| 6. Dr. Albert F. Kelso | American Association of Colleges
of Osteopathic Medicine |
| 7. Dr. Otha W. Linton
Director of
Government Relations | American College of Radiology |
| 8. Dr. Stephen Gelbach | Society of Teachers of Family
Medicine |
| 9. Dr. Joan S. Zaro
Administrative Officer
for Professional
Affairs | American Psychological Association |
| 10. Dr. William H. L. Dornette
President - Elect | American College of Legal Medicine |
| 11. Dr. William M. Heller
Executive Director | United States Pharmacopeial
Convention |

PANEL 3
HEALTH REGULATION AND PROMOTION

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|--|--|
| 12. Dr. Franklin E. Mirer
Industrial Hygiene
Consultant | International Union
United Automobile Workers |
| 13. James C. Crawford
Vice President | National Reyes Syndrome Foundation |
| 14. Dr. Marjorie C. Becker
Assistant Dean/Director
Allied Health Education | University of Michigan at Ann Arbor |
| 15. Dr. Jerry J. Rodos
Associate Executive
Director | American Osteopathic Association |
| 16. Richard D. Remington
Past President | Association of Schools of
Public Health |
| 17. Dr. Alan J. Douma
Clinical Scholar | George Washington University |
| 18. Inez Hindszark
Project Director | Study of Credentialing in Nursing
American Nurses Association |
| 19. Dr. Sorell L. Schwartz
Public Affairs
Committee | Federation of American Societies
of Experimental Biology |
| 20. Dr. George J. Theobald, Jr.
Executive Director | National Hemophilia Association

American Blood Commission |

PANEL 4: RESEARCH CAPABILITY

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|--|---|
| 1. Dr. William R. Barclay
G.V.P. for Scientific
Publications | American Medical Association |
| 2. Dr. John I. Nurnberger | Society of Biological Psychiatry |
| 3. Dr. Howard J. Brinkley | Society for the Study of
Reproduction |
| 4. Dr. Joe W. Grisham
Chairman, Research
Committee | Association of Pathology Chairmen |
| 5. Dr. Robert M. Bock | American Society of Biologists
and Chemists |
| 6. Dr. John C. Partin
Program Director
Clinical Research
Center | Cincinnati Children's Hospital
Research Foundation |
| 7. Dr. Joseph A. Bellanti
President - Elect | Society for Pediatric Research |
| 8. Dr. John V. Bergen
Chairman, Government
Affairs Committee | American Association of Colleges
of Pharmacy |
| 9. Dr. Robert M. Berne
Chairman, Council
of Academic Societies | Association of American Medical
Colleges |
| 10. Dr. John R. Blinks
Chairman - Elect
Research Committee | American Heart Association |
| 11. Dr. Michael D. Lockshin
Chairman, Professional
Education Committee | Arthritis Foundation |

PANEL 4: RESEARCH CAPABILITY

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|--|---|
| 12. Dr. David L. Rabin | American College of Preventive
Medicine

Association of Teachers of
Preventive Medicine |
| 13. Dr. Melvin E. Jenkins
Chairman, Department of
Pediatrics and Child
Health | Howard University College of
Medicine |
| 14. Dr. Robert W. Gracy | American Association of Colleges
of Osteopathic Medicine |
| 15. Dr. William J. Williams
Chairman, Department
of Medicine | State University of New York
Upstate Medical Center |
| 16. Dr. J. A. M. Henderson
Chairman | Minority Biomedical Support
Program Directors Organization |
| 17. Dr. William N. Kelley
President - Elect | American Federation for Clinical
Research |
| 18. Dr. Susan R. Gortner
Interim Chairperson | American Nurses' Association
Council of Nurse Researchers

American Nurses' Association
Council on Nursing Research |
| 19. Dr. Erhard Haus | International Society of
Chronobiology

International Society for Research
on Diseases of Civilization and
the Environment |
| 20. Dr. Edwin H. Lennette
President | American Society for Microbiology |
| 21. Dr. Robert G. Waggener | American Association of Physicists
in Medicine

American College of Radiology |

PANEL 4: RESEARCH CAPABILITY

- | | |
|--|---|
| 22. Dr. Stephen D. Nelson
Administrative Officer
for Policy Studies | American Psychological Association |
| 23. Dr. Elliot D. Weitzman
Vice - President | Association of Sleep Disorders
Centers |
| Coordinating Secretary | Association for the Psycho-
physiological Study of Sleep |
| 24. Dr. Martin Rubin
Member, Examining
Board | American Board of Clinical
Chemistry |
| 25. Dr. Michael Gordon | Society of Teachers of Family
Medicine |
| | North American Primary Care
Research Group |
| 26. Berniece Burkhardt
Controller | The Living Bank |
| 27. Dr. Anne M. Briscoe | American Association for the
Advancement of Science |
| 28. Dr. Kirklyn Kerr
Assistant Dean
for Research and
Advanced Studies | Louisiana State University
School of Veterinary Medicine |

PANEL 5: UNIFYING CONCEPTS

- | | |
|--|---|
| 1. Dr. Mahlon B. Hoagland | Delegation for Basic Biomedical Research |
| 2. Dr. Wallace C. Frasher
Executive Vice President | American Heart Association |
| 3. Dr. Leonard D. Fenninger
Vice President for Education | American Medical Association |
| 4. Dr. Federico Welsch
Governmental Affairs Liaison | Association of Independent Research Institutes |
| Executive Director | Worcester Foundation for Experimental Biology |
| 5. Dr. Gerald Weismann | Arthritis Foundation
American Rheumatism Association |
| Chairman, Public Policy Committee | American Society for Cell Biology |
| 6. Dr. Michael Gordon | Society of Teachers of Family Medicine |
| | North American Primary Care Research Group |
| 7. Col. Robert E. Glasgow
President | Down's Syndrome Congress |
| 8. Dr. Robert M. Rice
Director, Policy Analysis and Development | Family Service Association of America |
| 9. Dr. Ernst Knobil
President - Elect | American Physiological Society |

PANEL 5: UNIFYING CONCEPTS

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|---|--|
| 10. Dr. Douglas M. Astolfi
Member, Board of
Directors | American Brittle Bone Society |
| 11. Lorraine V. Gress
Executive Director | The Living Bank |
| 12. Dr. Charles A. Kiesler
Executive Director | American Psychological Association |
| 13. Dr. Ceylon S. Lewis
Chairman, Board of
Governors | American College of Physicians |
| 14. Alan Bosch
Department of
Community Services | AFL-CIO |
| 15. Dr. Peyton E. Weary | Society for Investigative
Dermatology |
| 16. Dr. Martin D. Kamen | American Society of Biological
Chemists |
| 17. Dr. Frank E. Young
Member, Public
Affairs Committee | American Society for Microbiology |
| 18. Sister Rosemary Donley
President | Sigma Theta Tau, The National
Honor Society of Nursing |
| 19. Dr. Charles B. Arnold
President

Director | American College of Preventive
Medicine

Health Maintenance Institute
American Health Foundation |
| 20. Marjorie Guthrie
Founder/President
Emeritus | Committee to Combat Huntington's
Disease |
| 21. Dr. Rodney T. Houlihan | American Association of Colleges
of Osteopathic Medicine |

PANEL 5: UNIFYING CONCEPTS

- | | |
|---|---|
| 22. Dr. Ronald P. Kaufman | Association of Academic Health
Centers |
| 23. Dr. Christian Klimt
Member, Board of
Directors | Pennsylvania Diabetes Institute |
| 24. Eleanor S. Kohn
Chairman, National
Research Committee | Mental Health Association |
| 25. Dr. Ismet Karacan
Past President | Association for the Psycho-
physiological Study of Sleep |
| Member, Executive
Committee | Association of Sleep Disorders
Centers |
| 26. Dr. Theodore Cooper | Association of American Medical
Colleges |

SECTION C

Annotated Chronology of Process

April - December, 1978

- APRIL 29: In his address before the Annual Meeting of the American Federation for Clinical Research (pages 132-146), Secretary Califano initiated a new, open process to develop principles of a multi-year strategy to guide DHEW health research activities and announced that he had asked the Director, NIH to establish a process designed to provide opportunities for public participation in this effort and that a National Conference would be held at the NIH.
- MAY: The Director, NIH outlined a proposed process to the Secretary which consisted of four major steps: (1) development of proposed DHEW principles by each agency engaging in health research activities; (2) synthesis of the agencies' proposals; (3) presentation to a National Conference; and (4) publication of the Conference's outcome to solicit additional public comment (pages 147-148). Agencies were encouraged to solicit the advice of their advisory groups in developing their statement of proposed principles. The processes used by several agencies in developing proposed principles are described on pages 155-197.
- JULY: The Secretary established a DHEW Steering Committee, chaired by the Director, NIH, to guide this initiative (pages 149-151); invited over 1,000 professional societies and health organizations to submit suggestions (pages 290-291); asked Cabinet members and other Federal agency heads for their ideas (page 238); and requested the Institute of Medicine, National Academy of Sciences to conduct an independent review and analysis of the draft principles resulting from the National Conference (page 255).
- AUGUST: On August 2, the DHEW Steering Committee met with the Secretary to discuss the status of the initiative and plans for the National Conference (pages 198-208).
- On August 11, invitations to participate in the National Conference were mailed to over 1,000 professional societies and health organizations. This mailing included tentative Conference plans and major substantive areas to be addressed (pages 292-299).

On August 14, a draft DHEW Statement of Health Research Principles was developed and distributed to the DHEW Steering Committee (pages 209-211).

In mid-August, nominations for Panel members were received, recommendations developed and approved by the Assistant Secretary for Health and the Secretary, and all nominees were called and invited to serve. Formal letters of invitation from the Secretary were sent to Panel members shortly thereafter (pages 277-280).

In mid-August, an analysis and summary of all suggestions received from professional societies, health organizations and other Federal agencies was prepared for the Secretary's review.

SEPTEMBER:

On September 1, the draft DHEW Statement of Health Research Principles was forwarded to the Secretary, having received approval by the DHEW Steering Committee.

On September 15, the pre-Conference mailing was sent to all registered Conference participants, Panel members, and health organizations expressing an interest in the documents. This mailing included the Conference agenda, panel membership roster, draft DHEW Statement of Health Research Principles, summary of public suggestions received from professional societies and health organizations, summary of other Federal agencies' comments and Conference logistics (pages 300-322).

OCTOBER:

On October 3 and 4, the National Conference on Health Research Principles was held at the National Institutes of Health (pages 89-128).

DECEMBER:

The Conference Report was published and distributed for additional public comment (pages 3-87).

SECTION D

DHEW Process to Develop Draft Health Research Principles

This Section contains documents describing the Departmental process followed in developing the draft DHEW health research principles presented to the National Conference. The documents are in chronological order beginning with Secretary Califano's April address before the Annual Meeting of the American Federation of Clinical Research and include descriptions of the approaches used by three agencies to develop proposed principles which were later consolidated as part of the overall Department statement.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

As Delivered

REMARKS OF
SECRETARY JOSEPH A. CALIFANO, JR.
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
BEFORE THE
ANNUAL MEETING OF
THE AMERICAN FEDERATION FOR CLINICAL RESEARCH
San Francisco Hilton Hotel
San Francisco, California
April 29, 1978

I have come across the country to pay tribute to you -- and to signal the commitment of this Administration to the vital research enterprise you represent: a commitment that the President is determined to express not only in words, but in deeds.

In the process, I want to discuss a subject of intense interest to you and to me: the future of Federal support for health research.

I want to suggest an important new process that we in government and you in the research community should begin to support basic research: development, for the first time, of a multi-year strategy to guide allocation of limited government health research dollars.

I hope you will not think it presumptuous for a layman to propose a new strategy for a subject on which you are so well informed. Let me say in my defense that though I may be a new student of the issues in science and biomedical research, since January 1977 I have been getting a crash course.

I had scarcely taken office as Secretary of HEW when I was immersed in the ongoing controversy about the effectiveness and safety of Swine flu vaccine.

Since then my trial by fire has continued from one issue to another in which science, medicine, politics, religion, ethics, and human values either converge or collide, in ways all too familiar to you:

- Abortion
- Saccharin
- Psychosurgery
- Fetal Research
- Recombinant DNA

Just this week, based on research into the dangers posed by asbestos, we launched a public information campaign to warn past workers of the health risks they face from asbestos exposure.

What have I learned from fifteen months of all this? Several things.

I have learned how critical it is to have a firm core of scientific knowledge upon which to base policy decisions. When I launched the Department's anti-smoking campaign, I knew it would arouse controversy, but I also knew that the effort was soundly and firmly based on painstaking and convincing scientific research.

I have learned the importance of working out, what Don Fredrickson calls, "technical consensus" on controversial scientific issues -- and of doing so in the open, not behind closed doors. When I was faced with difficult questions of immunization policy -- not the least of which were lack of public confidence as a result of the Swine flu program -- we held important meetings in the open and solicited a broad range of scientific and technical advice in an effort to find a common ground of expertise upon which to build. When I eventually made my decisions, the public knew everything I knew and was thus better able to judge them.

And I have learned that at the core of many health problems and controversies that government must resolve today is the dilemma created by enormous and pressing needs and limited resources. Indeed, in no other field is that dilemma more sharply posed -- or more important to resolve -- wisely and fairly -- than in health, and health research.

The Federal government has become the dominant force in biomedical research not only in this country, but increasingly, throughout the world.

It supports the largest health research establishment in the world today. HEW's support for health research amounted to an estimated \$3.4 billion in 1977 -- over 60 percent of the nation's total expenditure for such research, and almost 80 percent of the Federal health research effort.

The National Institutes of Health today oversee a research budget of \$2.7 billion in support of 15,000 principal investigators including 13,000 research grantees in non-federal institutions.

These are impressive numbers -- and all the more impressive when we reflect that they represent a relatively recent development. The Federal Health Research enterprise has existed for less than a generation.

In that brief span, we have realized some significant achievements -- achievements with which you are intimately familiar and for which you are largely responsible: unraveling the mechanisms of heredity; gains against rheumatic heart disease, hypertension, and rubella; new medicines derived from better understanding of the chemical basis for communication in the nervous system; the Salk and Sabin polio vaccines.

Each of these achievements reveals the march of our national health effort in just the right cadence, from basic research to applied research to technology transfer.

It is important, I think, to dwell upon these accomplishments; they are important justifications -- though hardly the only ones -- for our large research investments: justifications that the American people can easily grasp.

Yet, though the vital signs for our research enterprise remain good, some danger signals have appeared in recent years. As you well know, the

great expansion of the National Institutes of Health took place between 1955 and 1968, and not in the decade since then.

Last July, President Carter ordered a thorough-going review of Federal support for basic research. It turned up some sobering facts:

- Over the past ten years, Federal support for basic research has declined by nineteen percent in constant dollars;
- The quality of scientific plant and equipment at our great institutions has badly deteriorated;
- Research opportunities for young university scientists have been declining -- and so the percentage of young scientists on our faculties declined from 43 percent in 1968 to 27 percent in 1975: a chilling omen for future scientific achievement.

In the health field, there were, for example, serious efforts in the early 1970s to cut back on funding for biomedical research, under the guise of containing health expenditures.

It was foolish to think that we could make significant savings by cutting back biomedical research. The total spent for biomedical research, after all, is less than four percent of our nation's health expenditures. Contrast that with the 40 percent spent -- too often profligately -- on hospital care and the additional 20 percent spent on professional fees.

Realizing this, and deeply concerned about the nation's future research capacity, President Carter last fall determined that we should halt this downward drift and reverse it. The President directed a new emphasis on basic research in Federally supported science programs. The President's

fiscal 1979 budget for NIH contains a direction to reprogram \$93 million more to basic research.

This move to begin to redress the research balance is a significant step. It represents a commitment that is an important part of my message to you today. And the state of the research enterprise remains good, even if the growth spurt of a decade ago is not likely to recur soon.

The size and quality of the program for this meeting attest to the vigor of current medical research in this country. The excellence of our health research is also evidenced by the frequency with which Americans win the Nobel prize for medicine or physiology. In the last two years, five Americans received this award.

Thus, the President's commitment to basic research and the present stability of your efforts are encouraging indicators. But every day brings home more forcibly to us in government the limits on our resources -- limits on the amount of basic research, limits on the ability of research to help with some of the truly gargantuan health problems facing the nation -- limits that will be with us for the foreseeable future.

In an era in which resources for basic research are limited, we must develop a better strategy to guide the allocation of the federal research dollar. A multi-year plan will serve to level out the annual appropriations fluctuations that make rational research planning so difficult.

It is for this fundamental reason that I want you to help me set in place a new process by which HEW can develop a multi-year plan for health research.

At present, we do have decisions -- often made well -- about allocating funds within particular disciplines, or specific, relatively narrow areas of concern. But we do not have an across-the-board strategy for health research that assesses research and health needs in a systematic and comprehensive way.

Too often -- and I recognize that we in the Executive Branch, as well as those in Congress, are hardly free from blame -- our research dollars may go to popular causes, to the disease of the month, rather than to scientifically important endeavors. Too often, our research dollar may be overconcentrated in particular areas at the expense of other, equally valid and important spheres of inquiry. Too often, we do not ask whether our health research effort bears a reasonable relationship to the basic burden of illness in America -- including mortality, disability, and cost.

A multi-year strategy for basic health research, covering at least five years, is, in my judgment, an extraordinarily important goal:

- Such a plan will help us all, especially those of us in Government, resist some of the inevitable but not always desirable pressures that attend the distribution of substantial research dollars.
- Such a plan will bring an important measure of stability to the research enterprise by pointing out broad directions of government support for a more extended and realistic period of time than next year's budget cycle.
- Such a plan, by focusing on the important relationship between health research and health needs, will encourage

the creative interaction of ideas -- from the laboratory to the systems of health prevention, delivery, and regulation and from those systems back to the laboratory -- that will enrich the process of research itself.

- Such a plan will help us to tune our research efforts so that they bear an appropriate relationship to our nation's health needs.

It is far easier, I know, to agree upon the need for a strategy than to agree upon a strategy itself. For some, the mere mention of a five-year strategy, or any sort of strategy, may raise fears of well-intentioned but bureaucratic official interference with science.

I am acutely sensitive to this concern. And I am persuaded that development of a five-year research strategy will enhance, not diminish, the research effort. I also believe that the process by which we arrive at such a strategy is almost as important as the strategy itself.

Obviously, such a process should be conducted in the open, with full and robust discussion. We intend to seek advice and counsel from all quarters -- first and foremost from you, the leaders of the health research community, as well as from other interested parties. And we will, of course, consult fully with members of the Congress.

But the process will also be conducted with great care and deliberation. To that end, I envision the following steps in developing the five-year research plan.

- During the next three months, we will seek from all appropriate parties suggestions about the basic principles

that should inform the development of the plan. I have asked Dr. Fredrickson to develop and implement the most effective system for obtaining suggestions. This initial process of gathering and debating appropriate principles will include a conference on health research planning to be held at the National Institutes of Health this summer.

- After this initial consultation with the concerned communities, we will publish a tentative statement of the principles next fall and then seek extensive comments and criticisms before publishing the final principles early in 1979.
- During 1979, we will develop a more complete plan by, again, seeking advice, publishing a tentative plan, and then soliciting additional comments and criticisms -- with early 1980 as a target date for completion.

I recognize that as this process moves forward there will be intense debate. But that kind of debate and reassessment, in public, of the government-funded health research effort will, I am sure, be a stimulant, not a corrosive.

Indeed, I am confident that an energetic exchange of ideas among the research community, the government, the medical profession, consumers of medical services and others -- given a sharp focus by the objective of developing a multi-year plan to guide distribution of our limited research dollars -- will not only be novel, it will be of substantial benefit to all involved.

To give you a flavor of what I envision, let me share with you several tentative principles that might underlie a five-year plan. The first three principles are hardly controversial, but the two that follow, while perhaps unexceptionable in phrasing, may well be controversial in application. These principles are merely illustrative, and are neither immutable nor exhaustive.

- The most basic principle in my judgment should be this:
to maintain at a high level and to enhance our support
for fundamental research into biology and behavior.

The building of our current capacity represents a 25-year investment by the American people. It would be folly to jeopardize the network of competent investigators and institutions created so painstakingly over the years.

We intend to do everything in our power to strengthen this vital national commitment to knowledge development.

As we maintain our support for health research we should recognize several important dimensions of this principle:

- There must be freedom to pursue research topics that are not immediately relevant, for basic research is nothing less than a long-term investment and we cannot program or order neatly the mysterious and serendipitous ways in which new knowledge is developed.
- There must be diversity in the research that we support. The population-based life-sciences -- biostatistics, epidemiology, various behavioral sciences -- are at least

as basic to our understanding of health as the more affluent and popular consumers of research dollars, biochemistry and molecular genetics.

-- Another important dimension of this first principle is that serious attention must be given to renewal of the physical research plant, in addition to support for the scientists who seek to advance human knowledge. This plant is deteriorating and obsolescing. As the University Presidents' report on Research Universities and the National Interest stated: "The most serious reduction [in Federal support] has occurred in funds for new equipment and facilities and for upgrading existing plant." We must reverse that trend.

- A second principle is that we must assure that there are ample opportunities for young investigators.

We must consciously find ways to nourish the development of -- and provide research opportunities for -- the "Young Squirts." If research is to flourish, then we must appropriately structure competition between, as well as within, the generations -- for that competition has, so often in the past, been the driving, creative force in knowledge expansion.

- Third, basic research has to be accompanied by vigorous, thoughtful and, where appropriate, interdisciplinary applications. Seeking important uses for the fundamental knowledge developed by basic researchers is an essential element of the total

research effort. And this principle, too, has several important dimensions:

- Those engaged in the vital task of applications research must be in close touch with those who are doing the very best basic work.
- We should, perhaps, seek new ways of supporting those who understand and can make interconnections between basic applications research in particular fields. These valuable individuals -- scientific impresarios if you will -- bring together -- for their mutual benefit, and for the benefit of all -- scientists engaged in different kinds of research who have the potential for creative interaction. The connection not just between basic and applied research, but also among research disciplines, is critical.

We must recognize, in short, the different types of scientific roles and provide support to those who are concerned about transmitting the learning of the laboratory to the society at large.

- Fourth, our government-supported research must have a strong orientation toward improving the quality of our nation's health and effectiveness of this nation's health services.

Although we are spending ever greater amounts on health care in the United States -- more than \$180 billion in fiscal 1979 or some 9 percent of the nation's Gross National Product -- there is substantial question whether billions of dollars of those expenditures have had any impact whatsoever on the health of the American people.

An improved knowledge base is vital to the central problem of health care in this country: providing quality health care at a reasonable cost. Indeed, as the vaccines so dramatically demonstrate, breakthroughs in research are often the means by which we can simultaneously improve health and cut the costs associated with disease.

Giving vitality to this principle involves applied research that, in candor, has not yet received its share of attention from the Old, Young, or Young, Young Turks. Some say that you have grown accustomed to treating applied problems, especially those affecting health delivery, like orphans, dumping them on the doorsteps of the schools of Public Health.

You can no longer abandon your responsibility in this area. You must work with the schools of Public Health as full partners. We need the best of the talents that the medical schools and the schools of Public Health can bring to bear. And we must remember that medical schools outnumber schools of Public Health by more than 4 to 1.

This fourth principle raises fundamental issues of health science.

-- The principle may involve new attention to basic problems:

Problems like nutrition, or the aging of the population, or new methods of fetal research, or dealing with the bewildering set of questions surrounding detection and prevention, not simply cure, of environmental cancers. For example, this year we have requested an additional \$33 million -- a 20 percent increase -- for the National Institute of Child Health and Human Development to seek new, safe, and universally acceptable methods of family planning, to

explore methods of producing healthy babies by correcting fetal deficiencies and to examine behavioral issues relating to birth problems in teen and sub-teen mothers who smoke.

- The fourth principle may involve new attention to some of the disciplines I mentioned before -- disciplines like epidemiology and biostatistics; and behavioral studies that have important implications for national health problems. For example, I have asked that we undertake more research into the critical behavioral question of why people begin to smoke and what is an effective method of helping them stop if they want to do so.
- The principle may also involve addressing some of the most basic issues: What is good health? How much health care is enough? How do we measure the quality of health care?
- A fifth and final principle is that HEW-supported research must be more effectively oriented to develop knowledge bases that support not just some but all the health missions of the Department -- prevention, delivery, regulation, standard-setting, and cost control.

It is now time to take a look at the health research strategy for the Department as a whole. We should reexamine whether our research resources are properly distributed among our health components -- the National Institutes of Health, the Health Care Financing Administration, the Food and Drug Administration, the Alcohol, Drug Abuse, and Mental Health Administration and other components of the Public Health Service.

Should there be greater research capacity within the operating components of the Department in order to increase the feedback between researcher and operator? Should there be a different set of questions addressed by researchers in order to help carry out pressing health missions -- such as reducing dangers from environmental causes, or discouraging and preventing excessive alcohol consumption?

As I noted, these principles are tentative examples of the formulations that we should develop this year as a prelude to the drafting of a more comprehensive five-year research plan.

I recognize, of course, that there is an inherent tension in the effort to produce such a plan -- a tension illuminated by the contrast between the first three principles I mentioned, which are statements in support of research without any indication of the directions in which that research might go, and the last two principles, which involve a substantive orientation of our research effort.

But it is our fate to live in an era of limited resources. Our society must learn how to make difficult choices wisely, and with foresight. We must shape a process in which the inevitable tensions I have highlighted will be creative -- a process that will produce a strengthened research enterprise which pursues knowledge openly and freely, for its own sake of course, but also to serve the health needs of the American people.

Thank you.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : The Secretary
Through: U _____
ES _____

DATE: May 17, 1978

FROM : Director, NIH

SUBJECT : Development of DHEW Health Research Planning Principles

To meet your announced policy of seeking public advice in the development of health research planning principles for the Department, I suggest that a process be initiated which is designed to provide maximum opportunities for public participation and which involves the following major steps and timing:

1. Agency Development of Proposed Principles (tentative completion date: July)

Each agency engaging in health research activities would develop proposed DHEW health research planning principles. This would draw upon previous agency efforts. However, if appropriate, each agency now should be encouraged to solicit the ideas and suggestions of their respective advisory bodies.

I have already initiated activities to involve the Advisory Councils of the NIH in developing the NIH statement of principles as the current cycle of Institute Council meetings begins today. Further, the June meeting of the Director's Advisory Council, NIH, will be constituted as a public forum on planning principles. Participants will include representatives from the Institute of Medicine, other agencies in the Department and a small number of selected public participants to broaden the community from whom advice will be sought and to ensure that differing perspectives are represented.

2. Consolidation of Agencies' Proposed Principles (tentative completion date: August)

A unified document would be developed which suggests health research planning principles for DHEW and which reflects each agency's proposals. This document will consolidate agencies' views where appropriate and identify alternatives where consensus is not achieved.

3. Presentation to a National Conference (tentative date: September)

The proposed DHEW health research planning principles would be presented at a National Conference held at the NIH to elicit participants' views and recommendations. Planning for the conference will be undertaken in collaboration with other DHEW agencies, and I recommend that the Institute of Medicine also be actively involved.

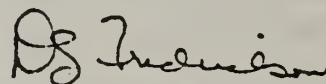
4. Publication of Conference's Outcome (tentative completion dates: draft--November; final--early 1979)

A document reflecting the results of the Conference would be developed for your review and published as a draft statement in order to solicit additional public comment. A final document, modified as appropriate based upon comments received, would then be published.

I anticipate that the successful conclusion of this effort will provide the basis for the subsequent development of a DHEW five-year health research plan. The approach for the development of the plan could be considered immediately after the national conference and also should be designed to provide full opportunities for public participation.

I have discussed this proposal with the Assistant Secretary for Health. Exploratory discussions have been held with the Institute of Medicine to ensure their involvement from the beginning.

If this proposal meets with your approval, guidance describing the process and schedule in greater detail should be prepared and sent to each Agency Head. My staff will be happy to undertake this if you wish.



Donald S. Fredrickson, M.D.

cc:
Assistant Secretary for Health

JUL 6 1976

MEMORANDUM TO: Assistant Secretary for Planning and Evaluation
Assistant Secretary for Health
Administrator, Health Care Financing Administration
Deputy Assistant Secretary for Health, Operations
Deputy Assistant Secretary for Health Policy, Research and Statistics
Director, National Institutes of Health
Administrator, Alcohol, Drug Abuse and Mental Health Administration
Director, Center for Disease Control
Commissioner, Food and Drug Administration
Administrator, Health Resources Administration
Administrator, Health Services Administration

SUBJECT: Principles of a Multi-Year Health Research Strategy

As you know, in April, I suggested that HEW begin an important new process to guide the allocation of limited government health research dollars. In my remarks to the Annual Meeting of the American Federation for Clinical Research, I sketched out a public, open process to develop principles for a multi-year research strategy.

The Director of the National Institutes of Health will take charge of the planning of this effort. It is also critical, however, that the Departmental agencies and organizations whose research activities are at stake be intimately involved in the planning and analysis this initiative will require to be successful.

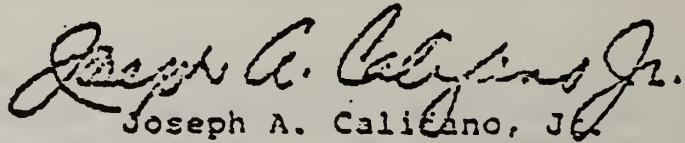
I am asking each of you to participate in an HEW Steering Committee that will guide the development of the principles of a multi-year strategy for allocating scarce dollars to health research. The Director of the National Institutes of Health will chair the Committee.

Each of you should canvas the top staff in your agency for ideas and comments, and, most importantly, act immediately to solicit advice from the scientists, researchers and the public affected by your agency's research programs.

The national conference -- scheduled for October --at which our proposed principles will be presented should be as fruitful and well-planned as possible. Please provide Don Fredrickson with any assistance he needs to bring off a top-flight conference.

The attachment to this memo sets out the timetable for developing our multi-year research strategy. We intend to stick to this timetable and meet the deadlines that it sets.

This is a unique and critically important effort. The process we are embarking upon will be essential to establish the foundation for developing a strategy to guide health research activities in the Department and in the Nation in the years ahead.


Joseph A. Califano, Jr.

Attachment

Schedule

1. Agency Development of Proposed Principles - July

Each agency engaging in health research activities will develop proposed health research planning principles. Agencies should solicit external advice either through their respective advisory bodies if appropriate or through some other mechanism. This effort is already well underway at the NIH, and at the direction of the Assistant Secretary for Health, other PHS agencies have initiated activities to develop proposed planning principles. This step should be completed by July 30.

2. Synthesis of Agencies' Proposed Principles - draft -- August; final September

A unified document will be developed which suggests health research planning principles for DHEW and which reflects each agency's proposals. This document will consolidate agencies' views where appropriate and identify alternatives where consensus is not achieved. A draft document should be available for review by the Steering Committee by August 22. A final document, revised to reflect the Committee's comments, will be completed and forwarded to the Executive Secretariat by September 10.

3. Presentation to a National Conference -- October 3-4, 1978

The proposed DHEW health research planning principles will be presented at the National Conference held at the NIH to elicit participants' views and recommendations. The HEW Steering Committee will review proposals concerning the structure of the Conference and the participation of other organizations including the Institute of Medicine.

4. Publication of Conference Results -- draft December; final - early 1979

A document reflecting the results of the Conference will be developed for my review and published as a draft statement in order to solicit additional public comment. The draft document which will have been reviewed by the DHEW Steering Committee should be completed by December. A final document, modified as appropriate based upon comments received will be published in early 1979.

January 11, 1979

HEW STEERING COMMITTEE FOR
DEVELOPMENT OF HEALTH RESEARCH PRINCIPLES

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Secretary of Health, Education, and Welfare

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COMMITTEE

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ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

In developing its research planning principles ADAMHA has sought input from a diversity of sources. In July, the Administrator of ADAMHA convened an advisory group of representatives of the National Advisory Councils of the three ADAMHA Institutes (NIAAA, NIDA, and NIMH) and of the initial review groups, and other interested persons. Drawing from the suggestions of this group ADAMHA submitted a draft set of principles in early August. Subsequently each of the Institutes convened meetings of its National Council and of the appropriate research initial review groups to consider both the ADAMHA and DHEW research principles. Attached are the letter from the Administrator, ADAMHA to participants of the July 28 meeting convened to advise ADAMHA on the development of the Agency's proposed principles and a list of participants.

SAMPLE

JUL 24 1978

Chief
Smithers Alcoholism Treatment
& Training Center
Roosevelt Hospital
428 West 59th Street
New York, New York 10019

Dear Dr.

I would like to thank you for agreeing to participate in the ADAMHA meeting on the development of principles or guidelines for a research strategy and to apologize for the short notice you have had. The meeting will be held on Friday, July 28, 1978 at 9:00 A.M. in Conference Room I on the third floor of the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland. A room has been reserved in your name at the Linden Hill Hotel, 5400 Pooks Hill Road, Bethesda, Maryland. It would be most helpful if you would make your own travel arrangements. You will, of course, receive the usual honorarium and be reimbursed for your travel and per diem expenses.

This meeting is being held in response to an initiative by the Secretary of the Department of Health, Education, and Welfare, calling for the development of principles to be used in forming a multi-year strategy to guide the allocation of limited government health research funds. The process the Department will follow for this initiative is described in the enclosed background document provided by the PHS. An information package with the following additional material is enclosed.

1. Remarks of Secretary Joseph A. Califano, Jr. before the Annual Meeting of the American Federation for Clinical Research
2. The NIH Forward Plan - Section One
3. A memo from Dr. Klerman to Secretary Califano concerning the DHEW Five Year Research Plan
4. The Road from Research to New Diagnosis and Therapy - Julius H. Comroe, Jr.

5. Proposal: Process under which the DHEW Health Research Planning Principles should be developed
6. Draft Statement of NIH Health Research Planning Principles (5/17/78)

This meeting will be concerned with developing general approaches or principles which can effectively be used to allocate finite research funds. I believe that this is feasible and that the development of a research philosophy will be helpful in ensuring that the best scientific studies will be supported in the coming years.

The enclosures include many principles that can be discussed generally and as they pertain to ADAMHA. An example of a set of variations of a possible planning principle relevant to research support by categorical institutes is given below and this should provide a sense of what I hope will be addressed at the meeting.

1. The objectives and specification of goals for each agency and/or institute should be developed in advance and research should be funded that has immediate and direct relevance to those goals.
2. The objectives and specification of goals for each agency and/or institute should be developed in advance but the agency should be free to support broad basic research that is not directly and immediately relevant to those goals.
3. The planning of research should be guided by scientific discipline rather than by disease orientation.

The obvious issue here involves the degree of latitude to be allowed various agencies in determining the role of basic research in their scientific programs. For example, should the NIDA feel free to solicit and encourage basic neuroanatomical studies of the hypothalamic-pituitary axis because it believes that such knowledge will be essential for the ultimate understanding of the behavioral activities of opiates? Or are such studies to be funded only by a particular institute specifically charged with carrying out such studies? And finally, is disease orientation the most productive starting point in developing a health research plan?

In thinking about your contribution to the meeting, please bear in mind that we will be discussing a national health research strategy that includes basic research, as well as research on health care and health services delivery, research on treatment efficacy, research

page 3

on potential value to regulatory agencies, and research on the
process of research itself.

I am looking forward to seeing you on the twenty-eighth.

Sincerely yours,

Gerald L. Klerman, M.D.
Administrator

Enclosures

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HEALTH SERVICES ADMINISTRATION

In response to the Secretary's initiative, Dr. George I. Lythcott, Administrator of the Health Services Administration (HSA), designated the Office of Planning, Evaluation and Legislation (OPEL) to oversee the development of the agency's proposed research principles. This office would be responsible for seeking input from the three bureaus which comprise the Health Services Administration. These bureaus are the Bureau of Community Health Services, the Bureau of Medical Services and the Indian Health Service. The Bureau Directors were contacted by the associate administrator for OPEL and given background information regarding the scheduled Conference and the proposed research plan. They were requested to canvas their staffs for ideas and comments concerning the Conference structure and the proposed research principles (Attachments A and B). To facilitate the incorporation of these comments into a draft agency statement, an HSA working group composed of OPEL staff was established (Attachment C). This draft statement was then returned to the Bureaus for review and comment to ensure that their views were adequately represented. After receiving Bureau approval, the draft principles were reviewed by the Administrator, his Special Assistant and the Associate Administrator for Regional Affairs. Their comments were incorporated by the working group into the draft statement and a final document produced. This statement, representing the Health Services Administration, was then forwarded to the Executive Secretary of the Steering Committee on Health Research Planning Principles.

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JUN 14 1976

Bureau Directors

Associate Administrator for
Planning, Evaluation and Legislation

Secretary Califano's Initiative--Development of DHEW Health Research
Planning Principles

As you may know, in his recent speech before the Annual Meeting of the American Federation for Clinical Research, the Secretary announced that a national conference will be held at the NIH this summer to seek public advice in the development of health research planning principles for the Department. A copy of the Secretary's speech is enclosed for your information. The attached memorandum to the Secretary from the Director, NIH, outlines a suggested process for the development of these principles to serve as the basis for a five-year health research plan for the Department. This process has been designed to provide maximum opportunity for public participation.

To guide this effort, Dr. Richmond has established a PHS Steering Committee comprised of the agency heads, the Deputy Assistant Secretary for Health Policy, Research and Statistics, and the Deputy Assistant Secretary for Health, Operations. Dr. Fredrickson will serve as Chairman of this Steering Committee. The agenda for the meeting, which will be held within the next few weeks, will include the following:

- o Review of the Proposed Process for Development of DHEW Health Research Planning Principles
- o Roles of Steering Committee and Planning Officers
- o Participation of the Institute of Medicine

As the first major step of the process (development of proposed DHEW principles by each agency) should be completed in early July, I suggest that you begin planning for this effort as soon as possible and initiate activities to solicit external advice if feasible.

Page 2

Dr. Lythcott will be asked to describe the approach that HSA will be using to develop the agency statement of proposed principles. To assist him please forward to my office by Tuesday, June 20, C.O.B. any ideas or suggestions for developing the HSA statement of proposed principles.

/s/William R. Gemma, Ph.D.

William R. Gemma, Ph.D.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES ADMINISTRATION
OFFICE OF THE ADMINISTRATOR

MEMORANDUM

TO : Bureau Directors

DATE:

7/18/78

FROM : Associate Administrator for
Planning, Evaluation and Legislation

SUBJECT: Principles of a Multi-Year Health Research Strategy

Dr. Lythcott will be participating as a member in the HEW Steering Committee discussed in the attached July 6 memorandum from the Secretary. You have already supplied material for the development of the proposed DHEW health research planning principles and offered suggestions on invitees to the October conference.

For a meeting planned for August 2, 1978, we need you to canvas your top staff for their ideas and comments on a set of health research planning principles and the conference in general. As the Secretary said in his memo, the organizations whose research activities are at stake should be intimately involved in the planning and analysis of this initiative for a multi-year health research strategy.

Please supply your comments no later than July 26, 1978.

15/
William R. Gemma, Ph.D.

Attachment

cc: Mr. Kelso
Dr. Lichty
Mr. Aspden
Mr. Popkin

Bureau Directors

JUL 21 1978

Associate Administrator for
Planning, Evaluation and Legislation

Principles of a Multi-Year Health Research Strategy

In the July 18 memorandum from this office, a request was made for ideas and comments by July 26, 1978 on the development of health research planning principles for the October conference at NIH.

Following the suggestion made at the July 18 meeting of HSA staff and Bureau Directors, a HSA working group will be established to prepare this agency's position. This group will meet Wednesday, July 26, 1978 at 10:00 a.m. in the Administrator's conference room.

Please bring your ideas and comments to this meeting.

William P. Germa, Ph.D.

cc: Mr. Kelso
Dr. Lichty
Mr. Asoden
Mr. Pookin

MAlesniak:bb:7-19-78

National Institutes of Health

The National Institutes of Health established two committees to assist in the development of agency proposed principles. The first was a working group comprised of Institute planning officers and Office of the Director planning staff. The second was an Overview Committee, chaired by the Director of NIH and comprised of Institute Directors and senior Office of the Director staff. These two committees developed draft NIH health research principles.

On May 15, 1978, the draft statement of NIH principles was sent to all members of the NIH Advisory Councils, requesting their review and comments. The two committees revised the NIH draft statement based upon many comments and suggestions received from council members. On June 15 and 16, 1978, the NIH Director's Advisory Council reviewed the NIH draft statement of principles. This meeting was augmented by consultants from various fields and members of the regulatory and health care agencies. Based upon this review, a final draft NIH statement of principles was prepared. On August 11, 1978, all NIH Advisory Council members were invited to submit additional comments and to participate in the National Conference on Health Research Principles held at NIH on October 3 and 4.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Members
NIH Advisory Councils

DATE: May 15, 1978

FROM : Director, NIH

SUBJECT : Secretary Califano's Initiative--Development of Health Research
Planning Principles

In a recent speech before the Annual Meeting of the American Federation for Clinical Research, Secretary Califano announced that a national conference will be held at the NIH this summer to seek public advice in the development of health research planning principles for DHEW. The successful conclusion of this activity will lead to the development of a five-year health research plan based upon the principles established. Your participation in this process is essential for the NIH and the DHEW in developing a document responsive to the Secretary's initiative.

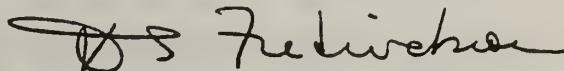
Attached are three documents, as follows:

- Attachment #1--Remarks of Secretary Joseph A. Califano, Jr., DHEW, before the Annual Meeting of the American Federation for Clinical Research, San Francisco, California, April 29, 1978.
- Attachment #2--Proposal outlining the process under which the DHEW health research planning principles would be developed.
- Attachment #3--Draft statement of the NIH health research planning principles.

Each Agency within the DHEW which engages in health research is involved in this initiative and will establish its own process to develop health research planning principles. Agencies' statements of principles will be consolidated for presentation to a national conference for review and recommendations to the Secretary. I believe that it is important to obtain your input as early as possible in this DHEW effort so that the NIH statement reflects the views of as broad a health community as is possible, given the timing of this initiative.

Towards that end, I would appreciate your review of the attachments, and your ideas and views on how attachments 2 and 3 might be improved and amplified for presentation to the national conference. I realize the difficulty involved in responding in a considered manner to documents which you do not have sufficient time to review. However, as

you can see from attachment #2, the timing of this process is extremely constrained. I encourage you to send written ideas to your Council's Institute Director. If your ideas could be received within a week, or at the most two, following completion of your Council meeting, they would be extremely useful to me in formulating an NIH statement.

A handwritten signature in dark ink, appearing to read "Donald S. Fredrickson". The signature is fluid and cursive, with a large initial "D" and "S".

Donald S. Fredrickson, M.D.

Attachments (Not Included)

cc:
B/I/D Directors
OD Staff
B/I/D Planning Officers
PPE Directors
Mr. Habel
Ms. Braymer
Mr. Mansfield
Mr. Miller

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF HEALTH

TO : Members
NIH Advisory Councils

DATE: August 11, 1978

FROM : Director, NIH

SUBJECT: Plans for National Conference on Health Research Principles

Plans for the National Conference on Secretary Califano's initiative for the development of health research principles for the Department of Health, Education and Welfare are now taking shape. This Conference will be held October 3 and 4 at the National Institutes of Health. I wanted to take this opportunity to keep you informed of those plans and to invite you to participate, as public witnesses, in the Conference. Your suggestions early in this process were important in developing these plans, and I urge you to continue to participate in this important initiative.

The following attachments will give you an idea of the Conference planning to date:

- Attachment #1 - Conference Structure
- Attachment #2 - Major Foci of the Conference
- Attachment #3 - Composition of Conference Panels
- Attachment #4 - Conference Registration Form - Please note the return date of September 1, if you wish to register for the Conference.
- Attachment #5 - Hotel Information

If you wish to register for the Conference or provide written comments to be considered during the Conference, and so indicate on the registration form, certain pre-conference material will be sent to you during mid-September. This will include:

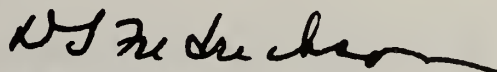
- Detailed information on the administrative and logistical management of the Conference,
- A finalized agenda with detailed scheduling of public testimony before each panel,

- A proposed statement of DHEW health research principles, organized around the five major Conference foci.
- A summary of all public comments for principles suggested for consideration which are received prior to the Conference, organized around the five major Conference foci. A broad community of professional societies and health organizations have been invited by Secretary Califano to provide suggestions and will be invited to participate, as public witnesses, in the Conference.

The Conference will result in a draft report of health research principles for the Department. This report will also be distributed widely for public comment and will form the basis for the later development of a multi-year strategy for health research in the Department.

The number of individuals who can be accommodated at the two plenary sessions of the Conference will be limited to about 500, due to the size of the facilities. Attendance at the plenary sessions will be determined by the return date of your registration form. The working panel sessions will form the bulk of the Conference; plenary sessions will be as brief as possible. The working panel sessions will be structured to allow for all who wish to speak to do so. Public testimony before the working panel sessions will be brief (10 minutes or less) and will be determined after registration forms are received. These sessions will be held in conference rooms accommodating 100-225. All participants will be expected to provide a copy of their testimony to the working panel at the time of their presentation. Your testimony should be structured around the Conference foci (Attachment #2) and the pre-Conference materials which will be mailed to you.

Once again, I thank you for your earlier suggestions and urge your continued participation. Since your participation at this Conference would be considered as that of a public witness, the NIH would not be able to defray expenses.



Donald S. Fredrickson, M.D.

Enclosures

(ATTACHMENTS #4 and #5 are not included)

ATTACHMENT #1

CONFERENCE STRUCTURE

October 3-4, 1978

National Institutes of Health

Bethesda, Maryland

First Day - October 3, 1978

Morning: Plenary Session

Opening Remarks and Charge to Panel Members:

- The Secretary of Health, Education, and Welfare
- The Assistant Secretary for Health
- The Director, National Institutes of Health

Late Morning

Through Afternoon: Panel Sessions -- Public Testimony

The Conference will divide into five separate panels structured around five major foci and receive public testimony from pre-registered witnesses. Testimony will be based upon the proposed statement of HEW health research principles. Witnesses will receive a copy of the proposed HEW principles and a short summary of prior public comments at least two weeks before the Conference and will be asked to submit a written statement of their remarks for the panels' use.

Evening: Panel Working Sessions

Panels will revise and refine the draft principles which relate to their foci based on the public testimony and prepare preliminary reports.

Second Day -- October 4, 1978

Morning: Panel Working Sessions

The panels will meet separately to review, discuss, and revise their preliminary reports.

Afternoon: Plenary Session

The panels would reconvene and present their reports.

ATTACHMENT #2

MAJOR FOCI OF THE CONFERENCE

Five major foci will serve as the substantive framework for the Conference. The first three foci address segments of the health research continuum and together provide a structure to consider the health research activities of all Department health agencies and the knowledge base for all Department health missions; the fourth addresses resources for research (institutional, manpower, facilities and equipment) and the fifth will serve as an integrating force to bridge and relate the others. The major foci are:

- FUNDAMENTAL RESEARCH -- This focus will address the need for fundamental research (the search for knowledge about fundamental processes of biology and behavior), the creative process which governs this type of research activity, and its role in improving the health of the public and contributing the essential knowledge base on which other Department health missions rely. This area will also encompass the issue of stability of support and the relationship of fundamental research to other segments of the health research continuum.
- CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH -- This focus will address the development of the knowledge base to support the health care function, the need to acquire, validate and apply new knowledge, the characteristics and requirement for applied, problem-oriented research, and the need to retain and strengthen the Department's pluralistic approach in support of applied research.
- HEALTH REGULATION AND PROMOTION -- This focus will address the further development of the knowledge base necessary for regulatory decisions and preventive and control measures, the requirement to communicate effectively the nature and inherent constraints of the regulatory process, and the need to explore more structured and creative interactions between the health research agencies and the agencies responsible for health promotion and regulatory activities.
- RESEARCH CAPABILITY -- This focus will explore the issues involved in assuring that the resources, both physical and human, necessary for the conduct of research are available.

- UNIFYING CONCEPTS -- This focus will explore concepts which provide the philosophic base for public funding of health research and the interactions among the different parts of the research continuum necessary to move from the development of new knowledge to the application of research findings. Included will be consideration of the need to reaffirm the Federal support of health research, what the public should expect as a return on its investment in health research, how to communicate effectively the nature of the scientific process, its limitations and benefits, bridges between fundamental and applied research, and new interactions and processes to be explored.

ATTACHMENT #3

COMPOSITION OF CONFERENCE PANELS

Five panels to address and receive public testimony on the five major Conference foci will be established. Each panel will consist of 15 members. Based upon recommendations from all Department health agencies involved in this initiative, the Secretary, DHEW, will select the panel members.

The composition of each panel will be as follows:

Chairpersons - The panel chairpersons will be individuals widely recognized in the substantive area to be addressed under each foci.

Membership - Panel membership will be heavily drawn from outside the Federal Government and will include leading members of the health research community, public interest and user groups, and private industry.

- Panel membership will also include members of the Federal Government, drawn from DHEW agencies directly involved in this initiative, as well as from other parts of Government.

AGENDA

THIRTY-SIXTH MEETING OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH
 June 15-16, 1978
 Building 31, Conference Room 10
 National Institutes of Health

THURSDAY, June 15

9:00 a.m. Opening Remarks Dr. Fredrickson
 Dr. Richmond, ASH

9:30 Attracting and Nurturing Young Scientists

Director's Advisory Committee Dr. Bondurant
 Consultant Dr. Neurath
 Government Dr. Klerman, ADAMHA

10:00 Committee Questions and Discussion

10:30 Coffee Break

10:45 Clinical Applications/Health Services

Director's Advisory Committee Dr. Bennett
 Consultant Dr. Marks

11:15 Committee Questions and Discussion

11:45 Fundamental Research

Director's Advisory Committee Dr. Comroe
 Consultant Dr. Tosteson
 Consultant Dr. Palade

12:15 p.m. Committee Questions and Discussion

12:45 Lunch

2:00 Regulatory Needs

Director's Advisory Committee Dr. Udenfriend
 Consultant Dr. Melmon
 Government Mr. Jellinek, EPA
 Dr. Miller, FDA

2:30 Committee Questions and Discussion . .

3:15 Coffee Break

3:30 p.m. General Overview

Director's Advisory Committee Dr. Eisenberg
Dr. Wildavsky
Mr. Hutt
Consultant Dr. Robbins
Government Dr. Smits, HCFA
Dr. Omenn, OSTP

4:30 Committee Questions and Discussion

5:15 Adjourn

FRIDAY, June 16

9:00 a.m. Opening Remarks Dr. Fredrickson

9:15 Committee Members' Opinions (5 min. each)

10:30 Coffee Break

10:45 Policy Regarding Recombinant DNA Research Dr. Fredrickson

11:15 Committee Questions and Discussion Dr. Fredrickson

12:00 Adjourn

Consultant/Non-DAC Commentators 6/15/78 Meeting

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SUMMARY OF THE
THIRTY-SIXTH MEETING OF THE
ADVISORY COMMITTEE TO THE DIRECTOR
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND
JUNE 15-16, 1978

Attracting Young Scientists

The committee considered the various aspects of Federal Government involvement in biomedical manpower training. The points noted in this regard included the following:

- The Federal Government must endeavor to have a major effect on the biomedical training system, even though it is not the main supporter of that system;
- There is a need for a clear statement of rationale for federal support in this area;
- The Government should aid universities by establishing training grants for junior staff positions with five to ten year commitments.

Educational opportunities for researchers was another major topic of discussion. There was general agreement that there is a need for continuing education in medical schools and also in the scientific community. A point was also made regarding the discrepancy between the deluge of medical school applicants and the dearth of qualified candidates for post-doctoral fellowships. Concern was also expressed regarding the need to create institutional stability for institutions that are responsible for the recruitment of talented people into the research field and the need for stabilizing the careers of individual young researchers. Other hypotheses and committee suggestions were:

- The most talented young researchers must be recruited, with particular emphasis on gifted M.D. and minority researchers;
- Federal support must be sought to encourage an increase in innovative research;
- There is a need to attract talented researchers into generally unattractive fields which have a high public health significance;
- Many more scientists should be encouraged to try their hand at research to determine whether they have research talent and expectations should be changed in order to allow those who are not gifted at research to achieve a smooth transition to an attractive career alternative;

- Biomedical professionals are generally better at their respective jobs for having acquired research experience;
- There is a need to determine how federal policies can be changed to deal with researcher attrition rates.

Regulatory Needs

The committee entertained a discussion of the ideal level of interaction between basic researchers and regulatory agencies. The resultant suggestions ranged from a nearly complete separation of efforts to programming an effort within N.I.H. towards the problems facing regulators. Those speakers representing regulatory agencies suggested that the N.I.H. could assist in developing short-term, more economical toxicological testing. It was pointed out that there is also a need for developing better methods of interpreting test results and that adequate tests are still nonexistent in the areas of neurobiology and behavior.

There was general agreement that it is difficult to conduct basic research in a regulatory environment, where first priority must be accorded to policing and application functions. The question of interfacing was further complicated by the assumption that regulators generally consider that the scientific community has not been as responsive to regulatory needs as possible. The majority of the group was in agreement that a dialogue is needed to bring together those who are involved in basic research and those who must deal with regulatory issues.

Other opinions offered in this discussion of regulatory needs included the following:

- Regulatory agencies are handicapped by a natural attention to narrow objectives which precludes involvement in a broader scientific inquiry;
- Scientific facts and methods should form the basis of all regulatory decisions;
- There may be a tendency to overestimate the ability of the scientific community to aid regulators; there are limitations on what basic science can accomplish;

- The N.I.H. might offer specific assistance to regulators in the development of new toxicological validation methods and the development of basic regulatory principles;
- Researchers may even profit from confronting the problems faced by regulators;
- There will be an ever-increasing involvement of private industry in the area of test development.

Fundamental Research

In this area, the committee dealt with the relevance of planning and the essentiality of basic research. It was generally agreed that scientific activities and opportunities of fundamental research must develop from the existing knowledge base and creativity of the investigators. Committee members supported the thesis that overplanning is an exercise in wasteful futility. There was also a consensus that a certain amount of research funds must be preserved for basic, creative research. Several members of the committee suggested that an irreducible part of all research monies be used to support fundamental research. Other points on which the committee achieved some consensus of opinion were:

- There is a need to explain to the public how scientific inquiry operates, how scientific knowledge is accumulated and the importance of non-mission oriented research;
- There must be a reaffirmation of federal support and a clarification of the role of the federal government in relation to basic research;
- There should be a move away from placing short term (e.g., five year) planning constrictions on fundamental research; longer commitments are desirable;
- There is a need to more clearly define fundamental and applied research;
- There must be a recognition of the importance of diversity and freedom to pursue ideas in fundamental research.

Other suggestions entertained by the committee included the following:

- There is a need to encourage greater effort in certain population-based aspects of fundamental research;
- There is a need to emphasize the broader social values that accrue from fundamental research.

Clinical Applications/Health Services

The Committee discussed at some length the issue of N.I.H. involvement in applied research. There was a general consensus that biomedical research is best conducted on a continuum from basic research through clinical application. There was also general agreement that the N.I.H. should be involved in some degree of applied research, though opinions as to the degree of such involvement varied. Other points for discussion in the area of N.I.H. involvement in applied research included the following:

- Research and development must be distinguished from one another for purposes of funding;
- The distribution of funding for applied research within DHEW should be clarified, and eligible researchers should be made aware of the methods of access to such resources;
- There are obvious advantages to an agency supporting applied research for its own use;
- Commercial resources should be considered by N.I.H. in the realm of application. It was suggested that the Federal Government lacks a policy for utilizing "civilian" technology to complement its research efforts;
- The DHEW must explore applications of new knowledge acquired in the health service field, and must assist in disseminating this new knowledge to appropriate groups;
- The N.I.H. must perform a health services research role while not undermining the primary function of basic research;
- Health services research should not be confined to a single institution, but is more effectively dealt with by several agencies.

Another major topic for Committee discussion was the potential involvement of private industry in the application of basic research. Committee comments were favorable regarding such utilization of the private sector. Opinions on this topic were as follows:

- That the private sector rightfully plays a major role in translating basic research into practical applications and delivering them to the public;
- That DHEW should examine its interaction with industry to determine how industry can be employed to provide a faster, more efficient translation and delivery of knowledge;
- That there is a need for review of the adverse effects of certain Government regulations and policies on basic research and applied research in the private sector;
- That patent laws of relevance to N.I.H. must be revised and rewritten in order to encourage the investment of private industry in applied research.

There was some discussion of the relationships between N.I.H. and various other institutions. Some of the major points made in this context were:

- The need exists for strengthening organizational ties between N.I.H. and the major academic health centers in order to better relate research efforts to health needs;
- Training programs in the disciplines of population-based medicine should become a commitment of the clinical departments of our schools;
- There is a need for bridge-building between Government, industry and the health centers so that efforts in basic research and application may be coordinated.

Additional points included the following:

- Serious consideration must be afforded to the premature application of new knowledge in the health care system;
- The time required for application of new knowledge has been shortened substantially over the past several decades;
- An appropriate peer review system for health services research is necessary to ensure that the maximum value will be extracted from each research dollar.

General Overview

In this area, the committee summarized and reiterated many of the ideas presented in the earlier sessions. On the subject of "Attracting Young Scientists", there was a brief discussion on the funding of training programs. Central to this discussion was the issue of training new scientists in relation to current research budget limitations. It was also pointed out that there is roughly a ten year gap between a given training enterprise and the resultant work effort.

On the topic of "Regulatory Needs", it was again noted that a need exists for greater interplay between regulators and basic researchers in the scientific community.

The members of the committee dealt with the issues surrounding "Fundamental Research" at greater length. There was agreement that the basic science budget should be kept separate and distinct from health services monies. There was also a suggestion that research energies should be redirected to encourage more innovative research. Other points and opinions relative to fundamental research expressed in this overview session included:

- Basic research should not be targeted for any particular (i.e., regulatory) objective;
- There is a need to provide a precise definition for the term "research plan";
- Non-budgetary improvements of the research enterprise might include improvements in the areas of paperwork, inflexible guidelines, and inflexible or inappropriate granting periods;
- Despite declining numbers, the involvement of M.D.'s as principal investigators should be continually encouraged.

In the area of "Clinical Applications/Health Services", the committee heard the following points and suggestions:

- Untried innovations should not be introduced into medical practice;
- There is a need for research to determine why people become patients;
- Improved health care and health habits will not necessarily reduce the cost of health care.

Meeting of the DHEW Steering Committee
for Development of Health Research Principles

Date: August 2, 1978
Time: 9:00 a.m. to 10:30 a.m.
Place: Hubert H. Humphrey Building
Room 610F

PARTICIPANTS

Joseph A. Califano, Jr., Secretary of Health, Education,
and Welfare
Mr. Richard Cotton, Deputy Executive Secretary, Office
of the Secretary

DHEW Steering Committee:

Dr. Donald S. Fredrickson, Chairman and Director,
National Institutes of Health
Mr. Henry Aaron, Assistant Secretary for Planning
and Evaluation
(Represented by Mr. Christopher Bladen)
Dr. Julius B. Richmond, Assistant Secretary for Health
Mr. Robert A. Derzon, Administrator, Health Care
Financing Administration
(Represented by Dr. Martha Blaxall)
Mr. Charles Miller, Deputy Assistant Secretary for
Health, Operations
Mrs. Ruth Hanft, Deputy Assistant Secretary for Health
Policy, Research and Statistics
Dr. Gerald L. Klerman, Administrator, Alcohol, Drug
Abuse and Mental Health Administration
Dr. William H. Foege, Director, Center for Disease Control
Dr. Donald Kennedy, Commissioner, Food and Drug
Administration
Dr. Henry A. Foley, Administrator, Health Resources
Administration
(Represented by Dr. Robert Graham)
Dr. George I. Lythcott, Administrator, Health
Services Administration
(Represented by Dr. William R. Gemma)

Invitees:

Dr. David A. Hamburg, President, Institute of Medicine
Mrs. Sarah Brown, Special Assistant to the President,
Institute of Medicine

Committee Staff:

Dr. Joseph G. Perpich, Executive Secretary and
Associate Director for Program Planning and
Evaluation, National Institutes of Health
Mr. Kurt Habel, Chief, Program Planning Branch
Office of the Director, National Institutes of Health
Ms. Nancy Braymer, Program Planning Branch, Office of the
Director, National Institutes of Health

AGENDA

- I. Opening Remarks and Charge to the Committee -- Secretary Califano
- II. Status of Activities to Date
 - A. Process and Schedule for Development of Principles
 - B. Announcement of Secretary's Initiative to:
 - Approximately 1,000 Professional Societies and Health Organizations
 - Cabinet Members and Heads of Selected Federal Agencies
 - Congress
 - Press
 - C. Development of Statement of Proposed Principles by Each Agency
 - D. Participation of the Institute of Medicine
- III. Plans for the National Conference: Issues for Decision
 - A. Proposed Conference Structure
 - B. Proposed Major Foci of the Conference
 - C. Proposed Method to Select Panel Members
- IV. Next Steps
 - A. Synthesis of Agencies' Proposals -- Draft Document Due August 22.
 - B. Synthesis of Public Suggestions on Principles -- Due August 22.
 - C. Selection of Panel Participants -- Completed by August 15.

DHEW Steering Committee
Minutes of Meeting
August 2, 1978
9:00 a.m. - 10:30 a.m.
Hubert H. Humphrey Building
Washington, D.C.

PARTICIPANTS

Joseph A. Califano, Jr., Secretary of Health, Education,
and Welfare
Mr. Richard Cotton, Deputy Executive Secretary, Office
of the Secretary

DHEW Steering Committee:

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National Institutes of Health
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and Evaluation
Dr. Julius B. Richmond, Assistant Secretary for Health
Mr. Robert A. Derzon, Administrator, Health Care
Financing Administration
(Represented by Dr. Martha Blaxall)
Mr. Charles Miller, Deputy Assistant Secretary for
Health, Operations
Mrs. Ruth Hanft, Deputy Assistant Secretary for Health
Policy, Research and Statistics . . .
Dr. Gerald L. Klerman, Administrator, Alcohol, Drug
Abuse and Mental Health Administration
Dr. William H. Foege, Director, Center for Disease Control
(Represented by Dr. J. Michael Lane)
Dr. Donald Kennedy, Commissioner, Food and Drug
Administration
Dr. Henry A. Foley, Administrator, Health Resources
Administration
(Represented by Ms. Sharon Barrett)
Dr. George I. Lythcott, Administrator, Health
Services Administration
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Dr. Joseph G. Perpich, Executive Secretary and
Associate Director for Program Planning and
Evaluation, National Institutes of Health
Mr. Kurt Habel, Chief, Program Planning Branch
Office of the Director, National Institutes of Health
Ms. Nancy Braymer, Program Planning Branch, Office of the
Director, National Institutes of Health

I. Opening Remarks by Secretary Califano

Secretary Califano opened the meeting by indicating that he considered the development of health research principles among the most important Department initiatives. He expressed his view that the development of health research principles through a public and open process is an effective approach for setting future health research agendas. This becomes particularly important as questions are raised about the level of investment in health research and as many ethical issues concerning health research are expressed. He also expressed his confidence in the individuals holding key health positions in the Department and his expectations that they will serve as a real asset to this initiative.

II. Key Dates in Initiative

Dr. Fredrickson outlined the following key dates between now and the National Conference, as follows:

- August 4 - Final cut-off date to receive any additions, revisions, etc. from each agency on their statement of health research principles.

-Date agreed upon by Committee members to forward nominations for chairman, co-chairmen, and members for each of five working panels at the Conference.

(Note: This information should be sent to Dr. Joseph Perpich, Associate Director for Program Planning and Evaluation, OD, NIH, Room 137, Building 1 Telephone number 496-3152.)

- August 11 - Mailing of letter of invitations and Conference plans to health organizations, professional societies and individuals requesting information.

(Note: NIH will handle this mailing centrally, based upon the master listing of organizations previously distributed to you or your staff. NIH also plans to send this information to members of their Advisory Councils and to invite them to participate in the Conference as public witnesses. Council members have actively participated in the process to date and have expressed interest in being informed of the Conference plans as they develop. If other agencies wish to send this information to members of their advisory bodies or other individuals, NIH will supply the packages to be mailed; the agencies, however, would be expected to do the actual mailing).

- August 14 - Draft synthesis of agencies' statements of principles to DHEW Steering Committee for review.
- August 15 - Selection of panel members by the Secretary, DHEW.
- August 22 - Review of synthesis of agencies' statement of principles by DHEW Steering Committee completed.
- September 1 - Submission of DHEW synthesis of principles to the Secretary, DHEW, for review. Submission of summary of public suggestions received to date (Note: Date changed from September 10).
- September 11 - Receipt of the Secretary's review of DHEW synthesis of agencies' principles.
- September 15 - Pre-Conference mailing, including synthesis of agency's principles, summary of public suggestions, agenda and scheduling of witnesses for panel sessions.
- October 3 and 4 - The National Conference

III. Discussion of Major Foci for Conference

Much of the meeting was devoted to a discussion of the five foci proposed, their meaning and their relationship to various agencies' concerns. Among the concerns expressed were the following:

- Under the foci entitled Unifying Concepts, it is important to include concepts on the adaptation process; that is, the bridges and interactions necessary between fundamental and applied research. (This has been included under Unifying Concepts).
- It was recommended that the Unifying Concept foci be viewed as serving an integrating function for the other foci and thus be moved from first to last (This has been done).
- The suggestion was made that new processes and interactions that may set new future directions be explored under Unifying Concepts (This has been included).
- The question of the purpose and function of the Conference was raised in terms of the scope of the foci. Discussion centered on whether the principles developed under each foci should set health research priorities, justify Federal health research support, and/or address research of highest opportunity and yield. (It was generally agreed that the principles developed under each foci should include but go beyond the justification of Federal support of health research, but that the intent was not to delineate areas of specific research opportunity. The principles developed should provide the foundation for the second phase of the Secretary's initiative; namely, the development of a multi-year health research strategy which, based on the principles, which would serve as a guide to the future allocation of scarce health research dollars).
- It was noted that H.C.F.A. supports applied social research but also depends upon fundamental research for the knowledge base necessary in carrying out its mission. (It was pointed out that the Clinical Applications and Health Services Research foci would address H.C.F.A.'s applied research activities, and that the Fundamental Research foci was intended to address the knowledge needs of all health missions).

(Note: Attached is a revision of the general areas to be covered under each foci, reflecting the above discussion).

IV. Structure of the Conference

Due to limited lead time and the need to provide for broad public participation, it was generally agreed that the proposed Conference structure is reasonable.

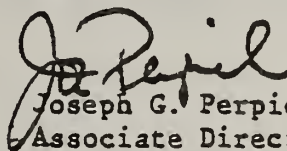
V. Selection of Panel Members

The following understandings were reached with respect to the composition of the five panels and the method of selecting members:

- The size of each panel will be limited to 15 members.
- Panel members will be more heavily drawn from outside the Federal Government, and public interest and user groups should, where possible, be represented.
- Panel chairmen should be widely recognized as experts in the substantive areas to be addressed by the foci.
- By decreasing the size of each panel and increasing non-Federal membership, it will not be possible for each agency and staff office represented on the DHEW Steering Committee to have a Federal member on each panel.

(Note: Each agency and staff office is to telephone nominations for panel chairmen, co-chairmen, public members and Federal representatives to Dr. Perpich, 496-3152, by close of business Friday, August 4. Dr. Fredrickson will forward proposals for panel membership to the Secretary shortly thereafter and keep the members of the DHEW Steering Committee informed).

Respectfully submitted,



Joseph G. Perpich, M.D., J.D.
Associate Director for
Program Planning and Evaluation

Enclosure

National Institutes of Health
Bethesda, Maryland 20014

August 4, 1978

Revised Proposed Major Foci of the Conference

Five major foci are proposed to serve as the substantive framework for the Conference. The first three foci address segments of the health research continuum and together provide a structure to consider the health research activities of all Department health agencies and the knowledge base for all Department health missions; the fourth addresses resources for research (institutional, manpower, facilities and equipment) and the fifth should serve as an integrating force to bridge and relate the others. The proposed major foci are:

- FUNDAMENTAL RESEARCH -- This section would address the need for fundamental research (the search for knowledge about fundamental processes of biology and behavior), the creative process which governs this type of research activity, and its role in improving the health of the public and contributing the essential knowledge base on which other Department health missions rely. This area would also encompass the issue of stability of support and the relationship of fundamental research to other segments of the health research continuum.

- CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH -- This section would address the development of the knowledge base to support the health care function, the need to acquire, validate and apply new knowledge, the characteristics and requirement for applied, problem-oriented research, and the need to retain and strengthen the Department's pluralistic approach in support of applied research.

- HEALTH REGULATION AND PROMOTION -- This section would address the further development of the knowledge base necessary for regulatory decisions and preventive and control measures, the requirement to communicate effectively the nature and inherent constraints of the regulatory process and the need to explore more structured and creative interactions between the health research agencies and the agencies responsible for health promotion and regulatory activities.

- RESEARCH CAPABILITY -- This area would explore the issues involved in assuring that the resources, both physical and human, necessary for the conduct of research are available.

- UNIFYING CONCEPTS -- This section would explore concepts which provide the philosophic base for public funding of health research and the interactions among the different parts of the research continuum necessary to move from the development of new knowledge to the application of research findings. Included would be consideration of the need to reaffirm the Federal support of health research, what the public should expect as a return on its investment in health research, how to communicate effectively the nature of the scientific process, its limitations and benefits, bridges between fundamental and applied research, and new interactions and processes to be explored.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF HEALTH

TO : Members
DHEW Steering Committee

DATE: August 14, 1978

FROM : Director, NIH

SUBJECT: Attached Draft DHEW Health Research Principles

Attached is a draft statement of proposed DHEW Health Research Principles. This represents both a synthesis and a compilation of each agency's contributions. This statement is organized around the five foci which will provide the structure for the National Conference on October 3 and 4.

This statement is not intended to represent a consensus among the agencies participating in this initiative. Where consensus seems to exist among agencies, this is identified; where views potentially unique to a particular agency were expressed in the agency's original statements, these are included and identified. The Conference should serve as the forum for reaching a fuller consensus than can be achieved at this point in the process.

Preparation of Document

In putting this statement together, we have done the following:

- o Synthesized agencies' statements of principles to the extent possible where the statements seemed supportive of one another. In many cases, this was difficult to judge since each agency's statement of principles was organized differently and suggestions were expressed in a variety of ways. In the attachment, where particular agencies appeared to concur around a view, this has been indicated by placing the agency's name in parentheses after the statement. Since the final draft of the NIH statement of principles was structured around the Conference foci, this statement was used as the organizational framework to indicate supporting views.
- o Added all agencies' suggested principles to the document which appeared to be unique to an individual agency. This required the assignment of suggestions to the Conference foci and compressing and combining some statements for purposes of brevity. These have also been identified by the agency name in parentheses following the particular statement.

Review of Document

In reviewing this document, it would be extremely helpful to take the following approach:

- o Write changes, additions, deletions on your copy and return your marked up copy to us.
- o Please return one integrated set of suggested changes for your agency or staff office.
- o If your agency or staff office has been identified as supporting a statement in the document incorrectly, simply cross out your identification with that statement. Conversely, if you are supportive of certain statements, but have not been identified as such, simply add that identification to the parentheses following the statement.
- o Please rewrite, change, or delete only those statements identified as unique to your agency or staff office's view. In this way, one agency will not be reshaping another agency's view.
- o Add any statements you wish. Please keep them as brief as possible and within the structure of the document.

Please send your marked up copies to Kurt Habel, Chief, Program Planning Branch, Room 205, Building 1, NIH (telephone number 496-1454) by close of business, Monday, August 21, 1978. The deadline is a very tight one which we must observe.

Next Steps

Once we receive your suggestions, the next steps will be:

- o Revision of the document based upon your suggestions. This must be completed and forwarded to the Secretary's office for review no later than September 1.
- o Review by the Secretary's office. A ten day period for review is required by the Secretary's office.
- o Based upon the above review, revision of the document and mailing it to all Conference participants. This must be completed by September 15. Also included in this mailing will be a summary of all public comments received to date.

Issue

Your advice is needed on the most appropriate approach to take in setting before the Conference participants those views on principles which are unique to a particular agency or staff office. Since this effort is designed as an open process, the public participants should know what the individual agency views are as well as those views where consensus among the agencies exists.

Also, the agencies and staff offices should have the opportunity to have their views known to the Conference participants. Since the Conference is structured to receive public testimony and to reach consensus on views, this question should be handled before the Conference. Two options seem reasonable; they are:

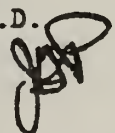
- o In the pre-Conference mailing of the proposed DHEW Health Research Principles, all agency and staff office identifications against statements can be dropped and if an agency so desires, their original agency statement of principles can also be included in the mailing.
- o In the pre-Conference mailing, the proposed DHEW Health Research Principles can retain the agency and staff offices identification against the statements.

The latter approach seems more effective and less costly, because it immediately sets before the participants each agency's input into the proposed DHEW statement and reduces significantly the amount of paper to be duplicated, mailed and studied by the recipient. There may be other approaches available to accomplish this. When you return your marked up copy of the proposed DHEW Statement of Health Research Principles, please give me your recommendations on this question at that time.

Also attached are copies of each agency and staff office's statement of principles. If you have any questions, please call Dr. Joseph Perpich, Associate Director for Program Planning and Evaluation, NIH, telephone number 496-3152. Thank you for your help in shaping this Conference and for your patience with the timing problems we have in moving this effort forward.



Donald S. Fredrickson, M.D.



Enclosures
(Not Included)

DRAFT DHEW HEALTH RESEARCH PRINCIPLES

PRESENTED AT THE NATIONAL CONFERENCE

(Included as Attachment #2 in the
Pre-Conference Mailing to Registered Participants
on September 15, 1978)

September 15, 1978

DRAFT DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH RESEARCH PRINCIPLES

The attached draft statement of DHEW Health Research Principles represents the combined suggestions of the following DHEW agencies and staff offices:

- Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)
- Center for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Care Financing Administration (HCFA)
- Health Resources Administration (HRA)
- Health Services Administration (HSA)
- National Center for Health Services Research (NCHSR)
- National Center for Health Statistics (NCHS)
- National Institutes of Health (NIH)
- Office of Assistant Secretary for Planning and Evaluation, Office of the Secretary (OASPE)
- Office of Health Policy, Research and Statistics, Office of the Assistant Secretary for Health (OHPRS)

Those agencies and staff offices that suggested statements of proposed principles are identified following each suggestion.

Background

The following statements concerning the scope of the Department of Health, Education, and Welfare (DHEW) health mission provide a context

for the development of health research principles:

- In brief, the primary health missions of the DHEW may be characterized as Research, Prevention, Care, and Regulation. Total Department expenditures for these missions in FY 1977 were approximately \$38.0 billion.
- In FY 1977, the DHEW paid 23% of the Nation's health bill; approximately 7% of the total DHEW expenditures for health missions was for research and development activities.
- There are four major health research agencies in the DHEW (NIH, ADAMHA, NCHS, and NCHSR). However, other agencies (FDA, CDC, HSA, HRA, HCFA) carry out health research in support of their primary missions. Total funding for health research and development in FY 1977 by all DHEW agencies engaged in health research was \$2.6 billion; support by the four major health research agencies was approximately \$2.5 billion (95% of the total).
- In FY 1977, NIH and ADAMHA provided 91% of all DHEW support for health research and development and 96% of the support for health research and development provided by the four major health research agencies. In 1977, NIH funding for health research was approximately \$2.2 billion; ADAMHA, \$153 million.

Introduction

In developing health research principles for the DHEW, it is important to recognize the following:

- DHEW health research principles must be sufficiently specific to provide a context and framework for the subsequent development of a multi-year health research strategy.
- The principles must encompass the full spectrum of health research conducted and supported by the DHEW (including biomedical and behavioral research, health services research, epidemiologic and demographic research, research on disease control technologies, research in statistical and survey methodology, and health research communications), and must relate health research to the other health missions of the Department.
- The principles are intended to serve as a structure for the subsequent development of a strategy to guide the allocation of limited Federal research dollars and to influence the manner in which the DHEW will carry out its health research activities.

Health Research Principles

This statement of principles is organized around five major foci:

(1) fundamental research, (2) clinical applications and health services research, (3) health regulation and promotion, (4) research capability and (5) unifying concepts. The first three foci address segments of the health research continuum and together provide a structure to consider the health research activities of all Department health agencies and the knowledge base for all Department health missions; the fourth addresses resources for research (institutional, manpower, facilities and equipment); and the fifth serves as an integrating force to bridge and relate the others. The concepts and principles proposed are intended to provide a context for formulating health research objectives and building a conceptual framework around which alternatives to meet these objectives may be developed. The principles do not address organizational changes or specific-program priority-setting.

FUNDAMENTAL RESEARCH

This focus addresses the need for fundamental research (the search for knowledge about fundamental processes of biology and behavior), the creative process that governs this type of research activity, and the role of fundamental research in improving public health and providing the essential knowledge base upon which other Department health missions rely. This focus also encompasses the issue of stability of research support and the relationship of fundamental research to other activities in the health research continuum.

- Principle -- A national commitment to fundamental research is essential to meet the full range of public health expectations. (NIH, FDA, ADAMHA)

- This national commitment must include long-term, stable support for fundamental research. This support is essential for the maintenance and strengthening of the scientific knowledge base related to all DHEW health missions. (NIH, ADAMHA, NCHSR, HRA, HCFA, NCHS, FDA)
- A reasonable level of Federal investment in fundamental research must be maintained to develop the knowledge base essential to support the health research continuum that extends through applied research to the prevention, diagnosis, and treatment of disorders and diseases and rehabilitation. This should be recognized as a long-term investment that provides the freedom for scientists to pursue diverse research topics that may not be immediately relevant to practical health problems. (NIH, ADAMHA, NCHSR, OHPRS)
- There should always be adequate mission outlets to bring basic research results to fruit and always enough basic research support to ensure that missions do not outrun their research base. (FDA)
- The development of new knowledge through fundamental research, and its application, although not a total solution, can have a significant impact on reducing health costs by improving our ability to prevent disease and the effectiveness of treatment

and rehabilitation. (NIH)

- The decision to fund fundamental research in a given area should be based upon an assessment of ongoing research and new scientific opportunity and evaluation for scientific excellence (which must remain the critical criteria for research support). (NIH, OHPRS, ADAMHA, NCHS)
- Investigator-initiated research must be fostered.
Investigator-initiated research underpins the health research network, provides a large measure of stability to the system, and plays a critical force in the development and expansion of knowledge. (NIH, FDA, ADAMHA)
- Basic research is surrounded by, and must relate closely to, an area of applications research. (FDA)
- Recognition must be given to a broadened concept of health factors and a research base developed to investigate them.
This base should include studies in the behavioral sciences and population sciences such as epidemiology and biostatistics.
(ADAMHA, NCHSR, FDA, NCHS, NIH)

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

This focus addresses the development of the knowledge base to support the health care function, the need to acquire, validate and apply new knowledge,

the characteristics of and requirements for applied, problem-oriented research, and the need to retain and strengthen the Department's pluralistic approach to the support of applied research.

- Principle -- To improve the quality of health care, prevent disease and reduce the burden of health care costs, the health care system requires, in addition to new knowledge developed at the fundamental level, the support of applied, problem-oriented health research. (NIH, FDA)

- The development of an adequate knowledge base for the fulfillment of health care missions must be supported. This includes strengthening all approaches to the solution of health problems as well as developing systematic ways to meet the needs of non-research health agencies for specific knowledge. (NIH, NCHSR, HCFA, HRA, ADAMHA, HSA)
- The validation of preventive and therapeutic measures before their introduction into the health care system must be assured, and standards for their application in medical practice determined. This includes the validation of new regimens in terms of their usefulness, efficacy, safety, cost-effectiveness and potential superiority over those already in use. (NIH, HRA, NCHS, FDA)
- The conduct of applied research to improve methodologies in the field of health and demographic statistics must be supported. This includes continuation and expansion of basic

measurement research in statistical and survey methodology to provide improved statistics on mortality, disease prevalence and incidence, health practices and new methods to facilitate epidemiologic analyses of large health data files. (NCHS)

- A strategy must be adopted for funding health research that includes provision for specific program expansions for the support of clinical applications, clinical trials and health services research activities. This includes the development and funding of multi-year, high-cost investigations and clinical trials as direct add-ons to specific agency programs where an adequate and available science base exists. The public sector, academic centers and appropriate elements of the private sector should be an integral part of this process. (NIH, ADAMHA, NCHSR)
- The scientific merit of health services research is a necessary condition for support. (NCHSR)
- The systematic dissemination of research results and related activities for consensus development must occur so that advances in knowledge are applied to the health care system as promptly and effectively as possible. (NIH, CDC, HRA, HSA, NCHSR, NCHS)
- Priorities for health services research support must be defined, and the social value of anticipated findings should be

a determining factor in this process. In defining priorities, the following should be considered: (NCHSR)

- Participation in the process by those responsible for providing the research support, as well as those directly associated with the problems and needs; (NCHSR, HRA)
 - Provision of flexibility for innovative proposals; (NCHSR)
 - Likelihood that the research will test assumptions on which current policies and delivery practices are based, provide the basis for developing new options for health services delivery or provide the means for monitoring performance of the health care system; (NCHSR, HSA, HRA)
 - The demand for the information likely to be generated by the study; (NCHSR)
 - The probability that the findings will be put to use. (NCHSR)
- DHEW's present pluralistic approach to the support of clinical applications and health services research must be maintained; planning and coordination among DHEW agencies need to be strengthened and new funding arrangements explored. (NIH, ADAMHA, CDC, HSA, HRA)

HEALTH REGULATION AND PROMOTION

This focus addresses the further development of the knowledge base necessary for regulatory decisions and preventive and control measures, the requirement to communicate effectively the nature and inherent constraints of the regulatory process, and the need to explore more structured and creative interactions between the health research agencies and the agencies responsible for health-promotion and regulatory activities.

- Principle -- The knowledge base necessary to protect the public health through the establishment of preventive measures, the conduct of health education and promotion activities, and the formulation of regulations must be further developed. (NIH, HRA, ADAMHA, OHPRS)
 - Between fundamental and applications research, there is mission-oriented fundamental research with a class of studies intermediate in character. This class of studies serves regulatory needs and has not been adequately addressed. The regulatory agencies of DHEW should be given the leading role in the support, planning and conduct of this research. (FDA)
 - Intensive and innovative cooperative efforts must be pursued by the government, health professionals, voluntary health organizations, and others in the private sector so that the public may be better informed and educated about the application of knowledge gained through research in order to

promote better health and to prevent illness. (NIH, CDC, HRA, ADAMHA)

- The public must be encouraged to improve health by adopting preventive measures and, when necessary, altering nutrition, environments, lifestyles and behavior to reduce the risk of disease, disability, and premature death. Such measures are more beneficial and less costly in the long-run than pursuing curative or rehabilitative approaches. (NIH, ADAMHA, CDC, HSA)
- Research should be supported to determine the most effective methods of providing preventive services and health education aimed at prevention, and a better balance should be sought between research focussed on prevention as opposed to research directed at therapies. (CDC, HSA, HRA)
- The public should be informed about the nature of the regulatory process, its strengths and limitations, including the constraints imposed upon it by the frequent need to make immediate decisions based on current knowledge. (NIH, FDA)
- Support of applied research to serve regulatory needs must be provided, and this research should continue to be conducted primarily by the regulatory agencies. (NIH, ADAMHA)
- New approaches must be explored to assure that the knowledge needs of the regulatory agencies are clearly and systematically

communicated to the health research agencies and that health research is responsive to these needs. (NIH)

RESEARCH CAPABILITY

This focus addresses the need to assure that the resources, both physical and human, necessary for the conduct of research are available.

- Principle -- Present research capabilities must be sustained and enhanced to assure future health gains. (NIH, CDC, ADAMHA, NCHSR, NCHS)
 - Human resources must be renewed and maintained: (NIH, CDC, ADAMHA, OHPRS)
 - It is essential to bring into the research community new investigators with new and innovative ideas and to provide them with support to capitalize on opportunities. This is necessary to train and maintain the next generation of investigators. Research careers must be kept competitive with other pursuits in order to attract and train outstanding individuals. (NIH, OHPRS, NCHSR, NCHS)
 - Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and medical careers. (NIH, ADAMHA, HRA)

- Recruitment of young researchers to areas of greatest national need and scientific promise must be encouraged.
(ADAMHA, FDA, NIH)
- Attention should be given to providing opportunities for promising clinically trained individuals with demonstrated aptitude for research to develop into independent investigators as well as for Ph.D.'s to enter clinical and other research disciplines. (NIH, ADAMHA, NCHSR)
- It is essential to provide opportunities to individuals who have just obtained health professional or research degrees to embark on academic and/or Federal research careers. (NIH, NCHSR, FDA)
- Programs aimed at the continuing education of health care practitioners must be encouraged so that new techniques, diagnostic tools, treatments and preventive measures which are the fruits of research can be passed on to the public through better medical care. (NIH, CDC, ADAMHA, FDA)
- Programs to support multidisciplinary, collaborative research approaches must be available. (NCHSR, HSA, ADAMHA, HCFA, HRA, NCHS, NIH)
- Major research activity at research and academic institutions such as health professional schools, graduate schools and

Federal and National laboratories must be fostered, and research support provided in a stable manner. Performance of research is inseparable from the learning process, enriching both directly and indirectly the quality of health care: (NIH, ADAMHA, CDC, FDA, NCHSR, OHPRS)

- Investigators and institutions need some measure of stability and should be buffered against radical short-term changes in policy. (NIH, ADAMHA, NCHSR, OHPRS)
- It is essential to provide an adequate level of long-term support to assure stability of training programs concerned with fundamental and clinical research in biomedical and behavioral disciplines. (NIH, ADAMHA, NCHSR, OHPRS)
- Physical resources must be renewed and maintained. This requires giving attention to both equipment and facilities. (NIH, ADAMHA, OHPRS, NCHSR, FDA)
- A continuous assessment of ongoing needs and resources should be pursued. (NIH, ADAMHA)

UNIFYING CONCEPTS

This focus deals with concepts that provide the philosophic base for public funding of health research and the interactions among the different parts of the research continuum necessary to move from the development of new

knowledge to the application of research findings. Considerations include the need: to reaffirm the Federal support of health research; to fulfill public expectations regarding a return on the public's investment in health research; to communicate effectively the nature of the scientific process, its limitations and benefits; for bridges between fundamental and applied research; and to explore new interactions and processes.

- Premise - The social context for the conduct of health research has changed to one of greater public accountability; a reaffirmation of the public commitment to health research and a restatement of the rationale for Federal support are needed. This reaffirmation must address the responsibilities and expectations of both the health enterprise and the public that underwrites it. (NIH, ADAMHA)

- In return for its investment in health research, the public should expect that:

- The knowledge that results from health research will serve to improve health, increase the fitness of children born into society, provide a better understanding of the environment in which people live and work, help each person to know something of his genetic makeup and how he might modify his life style to adapt to his environment and avoid disease, restore function and adaptation in the event of premature failure, ease the discomfort of the incurably ill and the aged, and assure that when life must end, it does so with dignity. (NIH, HSA, CDC, HRA,

ADAMHA, NCHSR)

- Resources for health research will be allocated so that public monies are spent wisely and the recipients are accountable for their use. (NIH, HSA, HRA, ADAMHA, NCHSR)

- Health research will be carried out in accordance with current social and ethical principles. Of special importance are the broad social, ethical, and legal implications of advances in biomedical and behavioral science and the technology derived from them. Research processes, guided by ethical considerations, must assure the protection of the rights and well-being of research subjects--both human and animal--and the health and welfare of laboratory workers, the public, and the environment. Ethical principles derived from a broad societal perspective, and reflecting the interests of both present and future generations, must underlie the determination of health science policies. (NIH, ADAMHA, HSA, FDA)

- Applied research, by its nature, is more amenable to planning than fundamental research. Although research support and mechanisms can be developed, the scientific activities and opportunities of fundamental research must develop from the existing knowledge base and creativity of the investigators. (ADAMHA, NIH)

- In order to meet these expectations, the Federal agencies conducting and supporting health research should:
 - Expect that public support as an allocation from the Federal treasury will continue. (NIH, NCHSR, ADAMHA)
 - Communicate to the public the nature of the scientific process, its promise and limitations so that the public will recognize that its support of health research is both a short and long-term investment. (NIH, OHPRS, ADAMHA)
 - Encourage the public to understand that knowledge is advancing to a stage of extraordinary refinement in certain areas, but that in many other areas there is still much unknown, and that a reallocation of resources to solve successfully specific health problems requires the existence of a knowledge base and research opportunity. (NIH, ADAMHA)
 - Recognize that the health research enterprise must again be successfully associated with symbols of high social value to recapture the imagination of the public, scientists and their public patrons included. (FDA)
 - Recognize that the health research community is not always in the best position to recognize or determine social

problems or needs. Therefore, those who are concerned with such problems or needs or are involved in trying to deal with them should have the opportunity to participate in defining research priorities. (NCHSR, OHPRS)

-- Expect that the public and health agencies will develop a partnership so that the safety, effect and value of new knowledge on improved health may be assessed prior to its widespread introduction into medical practice. (NIH, ADAMHA)

- Premise - The fulfillment of public expectations from health research is dependent upon the functioning of the health research continuum. To ensure proper functioning, the continuum of health research needs to be clearly defined. The definition must cover all types of research activity necessary to develop new knowledge and to translate it to human health application. It must also explain how those different parts of the research continuum interact with and depend upon one another. (NIH, FDA)

- The health research continuum begins with the performance of fundamental biomedical and behavioral research. These pursuits are deeply rooted in biology and use many disciplines to increase knowledge about living systems and synthesize it into useful form. The purpose of fundamental research is the extension of that knowledge to specifics that will improve human health. This improvement is dependent upon the

development and application of research findings and requires the assurance that the resulting techniques and procedures "are safe and effective. Successful application in turn requires diffusion to and acceptance by the consumer and health practitioner. (NIH, FDA)

- The advancement of knowledge necessary to improve health generally follows the logic of the research continuum. Advances in fundamental research underpin and provide the substance for the effective functioning of the entire process. However, advances may occur at any point on the continuum and may impact upon the other segments. Consequently, flexibility and adaptability are essential. (NIH, NCHSR, OHPRS)

- Adjacent to fundamental research in the health research continuum is a class of studies intermediate in character between fundamental and applied. They also use the tools of diverse disciplines and seek to synthesize old and new knowledge into generally consistent constructs. Thus they are fundamental in character. However, the generality sought is well circumscribed by the need for such studies, which derive mostly from social imperatives (e.g., avoidance of health hazards attending the development of technology). In that sense, they constitute applications research. The social need for such studies has not been widely understood. Consequently, mechanisms to foster and support them have not

been developed adequately. There is a need to develop such mechanisms. (FDA)

- The health research continuum ends with applications research which includes all studies designed to use available knowledge to improve human health. Research findings from diverse disciplines are applied to the development of procedures and techniques for solving health problems. Research assures the safety and effectiveness of such techniques and their widespread availability and acceptance by health practitioners and the public. (FDA)
- The interaction between fundamental research, applied research and its translation into improved health is a delicately balanced one, which is constantly being tuned by public expectations and changing research opportunities and which requires continuous reassessment and exploration of innovative approaches. (NIH, NCHSR, OHPRS)
- Effective placement of health research into human service requires effective mechanisms that identify and communicate to all engaging in health research the significance of new knowledge emanating from any point in the research continuum. These mechanisms must especially provide that those responsible for applications research are continuously aware of fundamental research activities so that they can judiciously modulate the latter to serve social needs without stifling creativity. The

mechanisms must also provide that those responsible for fundamental research are continuously aware of evolving social needs and of the potentiality offered by application research. Finally, the mechanisms must provide that those responsible for both fundamental and applications research are continuously aware of the needs, the directions and the challenges of mission-oriented fundamental research. (FDA, ASPE, NCHSR, OHPRS).

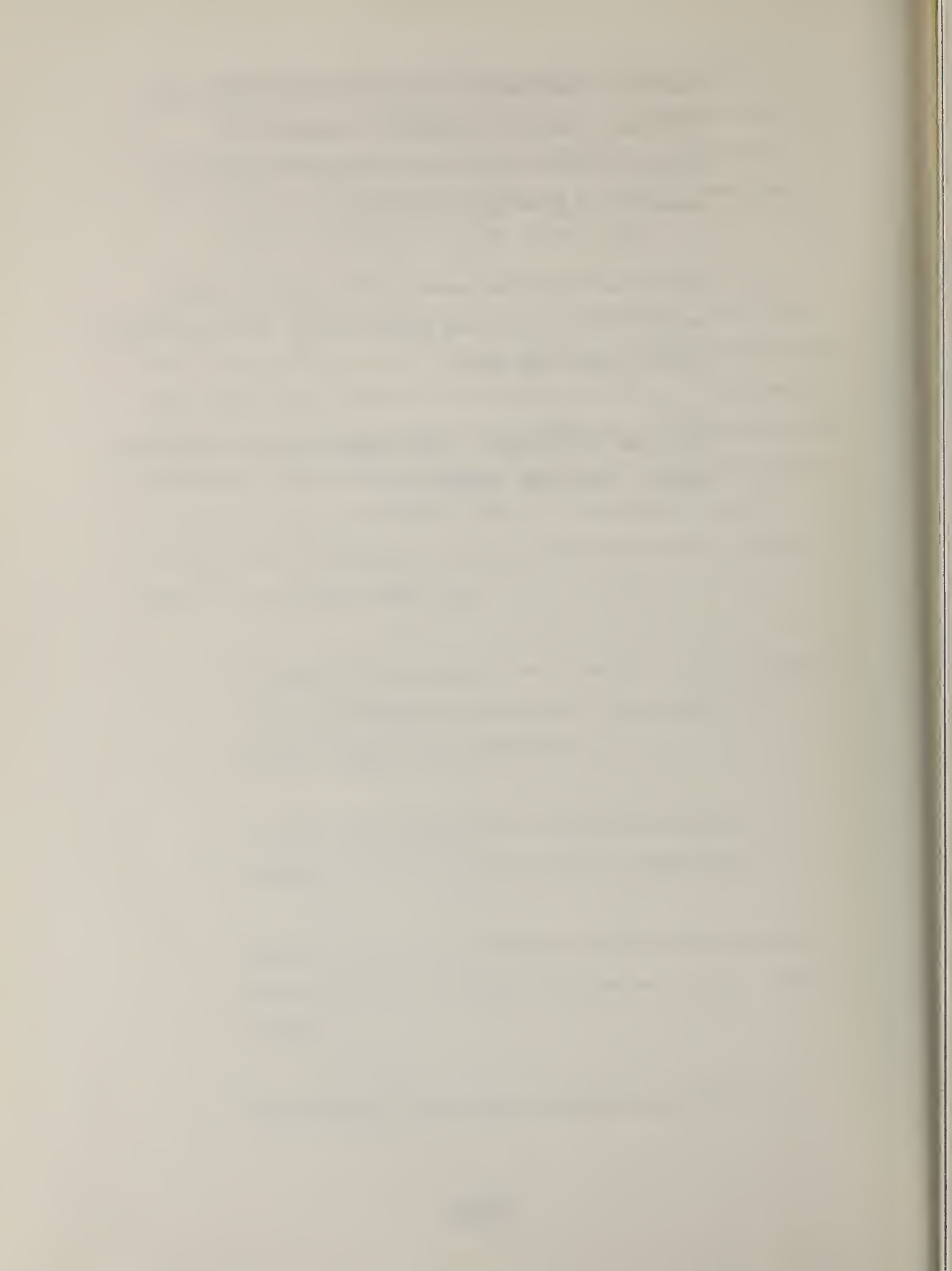
- Research in prevention of disease and disability is conducted at each point in the research continuum and is an integral part of many health research activities. Emphasis should be placed upon prevention research where opportunities exist, because in the long run prevention is more desirable than treatment.
(NIH, HSA, HRA, CDC, FDA, ADAMHA)
- Investments in areas of health research should be guided by many factors, including research opportunity, burden of illness measures, demographic trends, public perception of relative importance of different health areas, current state of the art, previous investment and return experiences, near term potential for new breakthroughs, problem areas identified through disease surveillance and investigation of disease outbreaks, interrelationship with other research problems, benefits which may accrue by elimination or improved treatment of disease, the perception of those concerned or involved in dealing with social problems or needs, and a continuing retrospective

assessment of health benefits attained through research expenditures. The relative importance of the above factors in allocating resources should vary between basic and applied research and will assist in seeking a balance between them. (ADAMHA, HSA, OHPRS, NIH, CDC, NCHSR, NCHS)

- Premise - The Federal approach to the conduct and support of health research is pluralistic. The DHEW agencies responsible for health care, disease prevention, regulation and research conduct and fund research in support of their primary missions. The mechanisms for interaction and communication among these agencies and among other non-Federal sectors of the health research enterprise need to be re-examined, and new processes must be explored to deal with problems identified. (NIH, ADAMHA, CDC, HSA, HRA, NCHSR, FDA)
 - The health research agencies and those that rely on research results must communicate their needs to one another in a systematic manner. (NIH, HRA, FDA)
 - The agency whose mission need is being met should be responsible for funding such research. (ADAMHA, CDC)
 - Applied or mission-oriented health agencies must be given responsibilities for research and research planning. (FDA, HRA, HSA)
 - The mechanisms of purchase of outside research should be

available to each agency through the media of grants and contracts to assure the adequacy of support for mission-oriented research which is beyond the intramural capacity of a given agency. (CDC, HRA)

- The role of the private sector in the conduct of health research must be reaffirmed and new avenues for interactions explored. (NIH, HSA, FDA)
- Mechanisms to strengthen international cooperation need to be examined. (NIH, CDC, ADAMHA, FDA)



SECTION E

External Participation in the Development of DHEW Health Research Principles

This Department initiative is predicated on seeking the broadest possible advice from all interested parties and providing maximum opportunities for public participation in the development of health research principles. This Section demonstrates how the advice of non-DHEW groups was solicited and contains documents dealing with the participation of other Federal Departments and agencies, Congress, the Institute of Medicine, foreign representatives, individuals invited to serve on the Conference Panels, and the public.



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

JUL 7 1978

MEMORANDUM TO: Cabinet Members
Director, Office of Management and Budget
Director, Office of Science
and Technology Policy
Chairman, National Science Foundation
Chairman, Council on Environmental Quality
Chairman, Nuclear Regulatory Commission
Administrator, Environmental Protection
Agency
Chairman, Federal Trade Commission
Chairman, Tennessee Valley Authority

SUBJECT: Principles of a Multi-Year Health Research
Strategy

In April I suggested that HEW begin an important new process to guide the allocation of limited government health research dollars. In my remarks to the Annual Meeting of the American Federation for Clinical Research (attached), I sketched out a public, open process that HEW would follow to develop principles for a multi-year research strategy to allocate HEW support for health research.

I ask that you provide me your suggestions and advice on the principles that ought to guide this multi-year strategy. It would be most helpful to have your suggestions by July 31, and it would also be useful if you would designate a staff contact. As we develop proposed guidelines, we will try to circulate them to obtain reaction from your office.

We will be presenting the proposed principles at a National Conference on October 3-4, 1978, to be held at the National Institutes of Health. I invite you to participate.

I have asked the Director of the National Institutes of Health to take the lead in coordinating this effort. He can provide you with any further information.

I attach great importance to this effort. The process we are embarking upon will be critically important in developing a strategy to guide health research activities in the Department and in the Nation in the years ahead. I look forward to receiving your suggestions.

Joseph A. Califano Jr.

Joseph A. Califano, Jr.

SEPTEMBER 15, 1978

SUMMARY OF COMMENTS FROM OTHER
FEDERAL DEPARTMENTS AND AGENCIES

In July, the Secretary of the Department of Health, Education, and Welfare asked other Federal Departments and agencies to provide suggestions and advice on the principles that ought to guide the development of a multi-year health research strategy for the Department. The Secretary's remarks to the Annual Meeting of the American Federation for Clinical Research provided the context for this request. Comments and suggestions have been received from the following:

- Department of Commerce
- Department of Energy
- Department of Labor
- Department of Justice
- Department of the Treasury
- Department of Transportation--Federal Aviation Administration
- Federal Trade Commission
- Nuclear Regulatory Commission
- Tennessee Valley Authority

This summary is organized around the five major foci which will serve as the substantive framework for the National Conference on Health Research Principles and which have been used in developing the draft DHEW Health Research Principles and in summarizing initial public comment. In adapting agency suggestions to this structure, some latitude has been required. In several instances, suggestions identified specific areas of health research which would contribute to meeting the commenting agency's responsibilities and mission needs. While these specific suggestions are reflected, this summary is oriented towards more general themes. Many of the responses did not address all of the areas or themes dealt with in this summary, nor do all commenting Departments and agencies necessarily subscribe to each point of view or suggestion included.

Comments received from other Federal agencies endorsed the Secretary's initiative, and several agencies specifically supported the five principles described in the Secretary's speech. The responses reflect initial suggestions; staff contacts have been identified to ensure that other Federal agencies have a continuing opportunity to provide comments and advice on draft reports resulting from the National Conference.

FUNDAMENTAL RESEARCH

- A number of Departments and agencies endorsed the concept that a national long-term commitment to support fundamental research is essential.
- Individual suggestions were that:
 - Evaluation for scientific excellence should remain a prerequisite for research support.
 - Appropriate emphasis should be placed on population-based life sciences, behavioral and epidemiological research.
 - Emphasis is needed in the following research areas: aging, underlying mechanisms of disease, causes of disease (including genetic determinants and environmental and occupational factors), identification of populations at risk and research to determine the relationship, if any, between stress and alcohol/drug abuse.

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

- The support of applied research to assess the effectiveness of health services and improve health status was endorsed by several agencies. Individual considerations here included the following:
 - Applied research can define current and future concerns facing the consumer of health services, identify those areas of the health sector which may be most responsive to change through competitive market forces, and help evaluate the impact of government regulation on the cost and quality of health care.
 - Cost-effectiveness should be considered in the support and conduct of applied research.
 - Further research is needed on the development of early identification tests for disease, screening techniques, health effects of current and new technologies, and control of lead contamination problems at indoor firing ranges.

HEALTH REGULATION AND PROMOTION

Comments which addressed the knowledge base necessary to protect the public through the establishment of preventive measures, the conduct of health education and promotion activities, and the formulation of regulations were:

- Early detection and prevention of health problems in the factory, office, home, and environment should receive emphasis. This would include elimination or reduction of hazardous exposures, medical monitoring of individuals at risk, continued development of data systems to facilitate research on hazardous substances, and the education of employers, workers and non-workers about health maintenance and safety.
- Intensive and systematic efforts should be pursued which are designed to better inform and educate the public about the application of knowledge gained through research and to encourage the public to adopt preventive measures and, when necessary, to alter behavior to improve health and prevent illness.

RESEARCH CAPABILITY

Within this area, a number of agencies endorsed the following concepts:

- Ample opportunities for young investigators, including programs to enhance research career development, should be assured.
- Approaches to foster multidisciplinary, collaborative research approaches should be developed.
- The maintenance and renewal of physical resources should be supported. Specific suggestions were:
 - Renovation and upgrading of existing facilities should be emphasized; priority should be given to established research institutions.
 - A block grant mechanism should be developed to support the renewal of research equipment in high-priority research fields.

UNIFYING CONCEPTS

Comments dealing with this focus were:

- Preventive medicine is the most appropriate means of cutting health care costs and increasing effectiveness.

- Preventive health research deserves an increasing share of the national health dollar.
- Mechanisms for interaction in health research activities should be enhanced within the Federal Government and with State agencies, private industry, and other countries.

September 7, 1978

Non-DHEW Government Contacts for
Health Research Principles Conference

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Justice: Mr. Bernard A. Borandi
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Room 6210, Dept. of Justice
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(202) 739-5126

Labor: Mr. Arnold Packer
Assistant Secretary for Policy,
Evaluation and Research
Department of Labor
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State: Mr. William Walsh
Biomedical Research Liaison
and Health Affairs Officer
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Treasury: Dr. Ronald Hoffman
 Senior Economist
 Department of the Treasury
 Office of Economic Policy
 Room 4454
 15th and Pennsylvania Ave., N.W.
 Washington, D.C. 20220

(202) 566-2281

NASA: Dr. Sherman P. Vinograd
 Director, Medical Sciences Branch
 Life Sciences Division
 SBR-3
 NASA Headquarters
 Washington, D.C. 20546

(202) 755-3723

TVA: Dr. Robert L. Craig
 TVA Medical Director
 Tennessee Valley Authority
 320 Edney Building
 Chattanooga, Tennessee 37401 .

(FTS) 854-2091

FTC: Mr. Michael R. Pollard
 Senior Staff Attorney
 Office of Policy Planning
 Federal Trade Commission
 Room 470
 6th and Pennsylvania Ave., N.W.
 Washington, D.C. 20580

(202) 523-1294

NRC: Mr. Saul Levine
 Director
 Office of Nuclear Regulatory
 Research
 U.S. Nuclear Regulatory Commission
 Washington, D.C. 20555

(202) 427-4341

SAMPLE

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20814

September 15, 1978

Dr. Sherman P. Vinograd
Director
Medical Sciences Branch
Life Sciences Division
National Aeronautics and
Space Administration
SBR-3/Headquarters
Washington, D.C. 20546

Dear Dr. Vinograd:

As the designee of the National Aeronautics and Space Administration for the Department of Health, Education, and Welfare initiative to develop health research principles, Secretary Califano has asked that I keep you informed of this initiative and plans for the National Conference. On behalf of Secretary Califano, I would like to invite you to attend the National Conference to be held on October 3-4, at the National Institutes of Health in Bethesda, Maryland.

The enclosed memorandum and attachments, which are being sent to all individuals who have registered for the Conference, describe the plans for the two-day proceedings. Although the Conference is structured to receive public testimony, you may wish to be present at one or more of the working panel sessions to hear the discussion or to present your views. If you plan on attending, please let Dr. Joseph Perpich, of my staff know as soon as possible so that space may be reserved (telephone 301/496-3152). Also indicate which of the five working panel sessions you would like to attend.

Once again, Secretary Califano and I appreciate your interest in this initiative and look forward to your possible participation in the Conference.

Sincerely yours,



Donald S. Fredrickson, M.D.
Director

Enclosure

SAMPLE



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

AUG 15 1978

The Honorable Richard S. Schweiker
Subcommittee on Health
and Scientific Research
Senate Committee on Human Resources
United States Senate
Washington, D.C. 20510

Dear Dick:

In April, I announced a new process to guide the Department's health research activities. In my remarks before the Annual Meeting of the American Federation for Clinical Research (attached), I sketched out a public, open process that HEW would follow to develop principles of a multi-year health research strategy.

My objective in initiating this process is to insure that the principles we develop take into account the views, perspectives, and concerns of individuals and organizations affected by our decisions. We have asked a broad range of professional societies and health organizations to send their suggestions on the principles the Department should adopt. Other Federal Departments and agencies have also been asked for ideas.

All agencies engaging in health research within the Department, and the Office of the Assistant Secretary for Health, are involved in this effort. I have appointed a DHEW Steering Committee to oversee this process. This Committee is chaired by Dr. Donald S. Fredrickson, Director, National Institutes of Health, whom I have asked to take the lead in coordinating this effort.

The comments received from the health community, the public, and other Federal agencies will be considered in formulating a statement of proposed HEW health research principles to be presented to a National Conference at the National Institutes of Health on October 3-4, 1978.

The process we are embarking upon will be critically important in developing a strategy to guide health research activities in the Department in the years ahead. We would, of course, be greatly helped by having your views and comments as we seek to develop these health research principles.

Sincerely,

A handwritten signature in dark ink, appearing to read "Joe", written over the printed name of Joseph A. Califano, Jr.

Joseph A. Califano, Jr.

Enclosure

ADDRESSES

The Honorable Robert Byrd
United States Senate
Washington, D.C. 20510

The Honorable Harrison Williams
Chairman
Committee on Human Resources
United States Senate
Washington, D.C. 20510

The Honorable Edward M. Kennedy
Chairman
Subcommittee on Health and
Scientific Research
Senate Committee on Human Resources
United States Senate
Washington, D.C. 20510

The Honorable Adlai Stevenson
Chairman
Subcommittee on Science, Technology,
and Space
Committee on Commerce, Science,
and Transportation
United States Senate
Washington, D.C. 20510

The Honorable Warren G. Magnuson
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable Howard Baker
United States Senate
Washington, D.C. 20510

The Honorable Jacob K. Javits
Senate Committee on Human Resources
United States Senate
Washington, D.C. 20510

The Honorable Richard S. Schweiker
Subcommittee on Health and
Scientific Research
Senate Committee on Human Resources
United States Senate
Washington, D.C. 20510

The Honorable James Pearson
Committee on Commerce, Science,
and Transportation
United States Senate
Washington, D.C. 20510

The Honorable Harrison Schmitt
Subcommittee on Science, Technology,
and Space
Committee on Commerce, Science,
and Transportation
United States Senate
Washington, D.C. 20510

The Honorable Milton Young
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable Edward W. Brooke
Subcommittee on Labor--HEW Appropriations
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable Tip O'Neill
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Harley Staggers
Chairman
Committee on Interstate and
Foreign Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Paul G. Rogers
Chairman
Subcommittee on Health and
the Environment
Committee on Interstate and
Foreign Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Olin Teague
Chairman
Committee on Science
and Technology
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Ray Thornton
Chairman
Subcommittee on Science, Research,
and Technology
Committee on Science and Technology
U.S. House of Representatives
Washington, D.C. 20515

The Honorable George Mahon
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Daniel J. Flood
Chairman
Subcommittee on Labor--HEW Appropriations
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

The Honorable John Rhodes
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Samuel Devine
Committee on Interstate and
Foreign Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Tim Lee Carter
Subcommittee on Health and
the Environment
Committee on Interstate and
Foreign Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable John Wydler
Committee on Science and Technology
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Harold Hollenbeck
Subcommittee on Science, Research,
and Technology
Committee on Science and Technology
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Elford Lederberg
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Robert H. Michel
Subcommittee on Labor--HEW Appropriations
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Alan Cranston
Chairman
Veterans' Affairs Committee
United States Senate
Washington, D.C. 20510

The Honorable Robert T. Stafford
Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510

The Honorable John C. Stennis
Chairman
Armed Services Committee
United States Senate
Washington, D.C. 20510

The Honorable John Tower
Armed Services Committee
United States Senate
Washington, D.C. 20510

The Honorable Ray Roberts
Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, D.C. 20515

The Honorable John Hammerschmidt
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Melvin Price
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Bob Wilson
Committee on Armed Services
U.S. House of Representatives

Dr. Russell W. Peterson
Director
Office of Technology Assessment
600 Pennsylvania Avenue, S.E.
Washington, D.C. 20510

The Honorable Howard Cannon
Chairman
Committee on Commerce, Science,
and Transportation
United States Senate
Washington, D.C. 20510



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

September 18, 1978

NOTE TO CONGRESSIONAL STAFF

As you may know, a National Conference on Health Research Principles will be held on October 3 and 4, 1978, at the National Institutes of Health. The Conference is part of a process initiated by the Secretary of Health, Education, and Welfare, Joseph A. Califano, Jr., to develop principles for a multi-year strategy to guide DHEW health research activities.

The Conference will be structured around five major areas: Fundamental Research, Clinical Applications and Health Services Research, Health Regulation and Promotion, Research Capability, and Unifying Concepts. Five panels will receive and consider testimony from pre-registered witnesses on the five foci. There will be two brief plenary sessions to open and close the Conference.

The Conference will result in a draft report of health research principles for the Department. This draft report will be circulated widely for comment and will be subject to an independent critique by a special committee of the Institute of Medicine of the National Academy of Sciences.

If you wish to attend the Conference, please call me on 496-3152 or Kurt Habel of our planning staff on 496-1454 by Friday, September 22. Space is very limited, but I will try to accommodate you. Enclosed is a copy of the pre-Conference material which is being sent to individuals who have registered for the Conference and which includes the draft DHEW Health Research Principles and summaries of public comments and suggestions from Federal Departments and agencies. Thanks very much.

/s/ Joseph G. Perpich
Joseph G. Perpich, M.D., J.D.
Associate Director for
Program Planning and Evaluation

Enclosure

ADDRESSES

SENATE

Ms. Laurel Blaydes
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Technology & Space
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Mr. William Gibb
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on Science, Tech. & Space
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5202 Dirksen Building
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Mr. Stephen Merrill
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Res., Cmt. on Human Resources
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Henry Jackson
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Mr. Terry L. Lierman
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1108 Dirksen Building
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Ms. Rebecca Beauregard
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Ms. Louise Ringwalt
Office of Senator
Alan Cranston
U. S. Senate
229 Russell Building
Washington, D.C. 20510

Mr. W. Featherstone Reid
Office of Senator
Warren Magnuson
U. S. Senate
127 Russell Building
Washington, D.C. 20510

Ms. Judy Robinson
Subcommittee on Employment,
Poverty, & Migratory Labor
Cmt. on Human Resources
U. S. Senate
A705 Immigration Building
119 D Street, N.E.
Washington, D.C. 20510

ADDRESSES

SENATE

Ms. Frances Paris
Mr. Lee Verstanding
Office of Senator John Chafee
U. S. Senate
3103 Dirksen Building
Washington, D.C. 20510

HOUSE OF REPRESENTATIVES

Ms. Jo Ann Glisson
Subcmt. on Health & the Environ.
Cmt. on Interstate & Foreign Com.
U. S. House of Representatives
2415 Rayburn Building
Washington, D.C. 20515

Mr. Stephen Lawton
Subcmt. on Health & the Environ.
Cmt. on Interstate & Foreign Com.
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Mr. Burke Zimmerman
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U. S. House of Representatives
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Congressional Research Service
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Ms. Marge Colloff
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Mr. Bob Kerr
Office of Rep. Andrew Maguire
U. S. House of Representatives
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Mr. Henry Neil
Subcmt. on Labor/HEW Appropriations
Committee on Appropriations
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2358 Rayburn Building
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Mr. Walter Sanders
Office of Rep. John Dingell
U. S. House of Representatives
2221 Rayburn Building
Washington, D.C. 20515

Ms. Jo Ann Shorey
Rep. Richard Ottinger
House of Representatives
240 Cannon Office Building
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Mr. Brian Smith
Office of Rep. Edward Patten
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Ms. Rita Kach
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323 Cannon Building
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Ms. Francine DePeyster
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Tim Lee Carter
2161 Rayburn Building
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THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

JUL 6 1973

David A. Hamburg, M.D.
President
Institute of Medicine
National Academy of Sciences
2101 Constitution Avenue
Washington, D.C. 20418

Dear Dave:

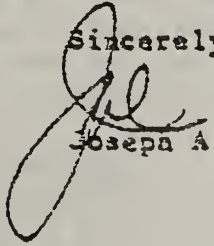
I recently asked Don Fredrickson to review with me the discussions that have been held with you and members of your staff concerning the participation of the Institute of Medicine in the development of health research planning principles for the Department. As you know, I believe this activity has major implications for the Department and am pleased that you share my enthusiasm for this initiative.

Although the Federal Government will retain responsibility for this effort, its success in large part will depend on the participation and contributions of the broader health community. The Institute of Medicine is uniquely constituted to reflect a wide spectrum of the views of this community.

Based on your discussions with Don, I have considered the activities that the Institute of Medicine might undertake as this effort proceeds. It would be extremely useful if the Institute of Medicine would provide informal advice and consultation in formulating plans for the National Conference. I also believe that an independent review and analysis by the Institute of Medicine of the draft principles that result from the National Conference would be constructive. I hope you will consider further how the Institute could be effectively involved, including the possibility of providing a focal point to solicit and draw together the ideas of the public prior to the National Conference.

I have asked Julia Richmond and Don Fredrickson to explore with you these proposals and any additional activities you might wish to undertake. I appreciate your interest and support and look forward to your continued assistance as this effort progresses.

Sincerely,


Joseph A. Califano, Jr.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

SEP 22 1978

Dear (See List of Addressees)

I am writing to express my appreciation--and that of Secretary Califano--for your willingness to participate in the work of the National Conference on Health Research Principles, scheduled for October 3 and 4.

The National Conference promises to be an important one for all those interested in future directions of health research. From the set of principles developed at this Conference will emerge the goals for health research toward which implementing strategy by the Department must then be directed. The end product of these processes, involving principles, goals, and implementing alternatives, will be a Five-Year Health Research Strategy for the Department, and accompanying budget, to be in place by the fall of 1979.

The Secretary initiated the Conference to seek the widest possible public advice in the development of the health research planning principles, on which all subsequent processes will depend. The role of the Institute of Medicine in these Conference proceedings is, of course, unique. Because of its mission and the nature and caliber of its membership, it is able to reflect--both authoritatively and with a high degree of objectivity--a wide spectrum of the view of the critically important health community. I am very pleased, therefore, that you agreed to serve as a member of the Institute of Medicine Committee that will review and advise independently on the draft principles.

As you know, David Hamburg has participated from the very beginning in the Department's initiatives in this area. He has been a most valuable resource to the Secretary, to Dr. Richmond, and to me; and I look forward to working closely with him, Sarah Brown, and the Committee for the next several months. Thank you very much for your willingness to cooperate.

Sincerely yours,

Donald S. Fredrickson, M.D.
Director

Institute of Medicine
Committee to Review DHEW
Research Planning Principles

Chairman: Irving M. London, M.D.
Director, Harvard MIT Division
of Health Sciences & Technology

MIT 16-512
77 Massachusetts Avenue
Cambridge, Massachusetts 021

Members:

Julius Axelrod, Ph.D.
Chief, Section of Pharmacology
Laboratory of Clinical Sciences
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National Institutes of Health
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Robert M. Ball, M.A.
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Institute of Medicine
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Thomas W. Bice, Ph.D.
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Lester Breslow, M.D., M.P.H.
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Joshua Lederberg, Ph.D.
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Gardner Lindzey, Ph.D.
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Center for Advanced Study
in the Behavioral Sciences
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Fredrick Mosteller, Ph. D.
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Irving J. Selikoff, M.D.
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Mount Sinai School of Medicine
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Daniel C. Tosteson, M.D.
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Burton A. Weisbrod, Ph.D.
Professor of Economics
Department of Economics
University of Wisconsin
7418 Social Science Building
Madison, Wisconsin 53706
(608) 262-6925

September 19, 1978

His Excellency Peter M. Towe
Ambassador
Embassy of Canada
1746 Massachusetts Avenue, N.W.
Washington, D.C. 20036

Dear Mr. Ambassador:

I have the honor to send you, enclosed, materials pertaining to the National Conference on Health Research Principles, which will be held at the National Institutes of Health, Bethesda, Maryland, on October 3 and 4. Testimony and discussions at this Conference will be used as the basis for presenting recommendations on HEW health research principles to Secretary Califano--principles which may apply to HEW's role in health research for at least several years.

If you would be interested in sending a member of your staff to this Conference as an observer, I will be grateful if your Embassy will call my office (Ms. Glenda West, 245-6174) not later than Friday, September 22 and give us the name, title, and address of the Embassy staff-member who will be attending.

Sincerely yours,

(Sgd) Laurence Wyatt

Laurence Wyatt
Director

Enclosure

IDENTICAL LETTER SENT TO AMERICAN EMBASSIES UNITED KINGDOM,
ISRAEL, ITALY, AUSTRALIA, SWEDEN, FRANCE, ARGENTINA, BRAZIL,
EGYPT, INDIA, U.S.S.R., THE NETHERLANDS, SWITZERLAND,
BELGIUM, MEXICO, AND JAPAN

ROSTER OF PANEL MEMBERSHIP

Conference Chairperson:

Dr. Donald S. Fredrickson
Director
National Institutes of Health
Bethesda, Maryland

Conference Staff:

Dr. Joseph G. Perpich
Associate Director for Program
Planning and Evaluation
National Institutes of Health

Mr. Kurt Habel
Chief, Program Planning Branch
Office of the Director
National Institutes of Health

Mr. George E. Presson
Executive Officer
Fogarty International Center
National Institutes of Health

Ms. Nancy Braymer
Program Planning Branch
Office of the Director
National Institutes of Health

Ms. Theodora Schulman
Conference Assistant
Fogarty International Center
National Institutes of Health

Mr. Charles Zellers
Program Planning Branch
Office of the Director
National Institutes of Health

PANEL 1

FUNDAMENTAL RESEARCH

Chairperson: Dr. Donald W. Seldin
Professor and Chairman
Department of Medicine
Southwestern Medical School
University of Texas
Dallas, Texas

Co-Chairpersons: Dr. Robert Berliner
Dean
School of Medicine
Yale University
New Haven, Connecticut

Dr. Mildred Cohn
Professor
Department of Biochemistry
and Biophysics
University of Pennsylvania
Philadelphia, Pennsylvania

Dr. Cyrus Levinthal
Professor of Biological Sciences
Department of Biological Science
Columbia University
New York, New York

Panel Members: Dr. John Barson
President
Oklahoma College of Osteopathic
Medicine and Surgery
Tulsa, Oklahoma

Dr. Floyd Elliott Bloom
Director
Arthur V. Davis Center
for Behavioral Neurobiology
Salk Institute
San Diego, California

Dr. Robert N. Butler
Director
National Institute on Aging
National Institutes of Health
Bethesda, Maryland

Dr. David R. Challoner
Dean
School of Medicine
St. Louis University
St. Louis, Missouri

Fundamental Research

Dr. John C. Eberhart
Director, Intramural Research
National Institute of Mental Health
Alcohol, Drug Abuse, and
Mental Health Administration

Dr. Bernice Grafstein
Professor of Physiology
Department of Physiology
Cornell University Medical College
New York, New York

Dr. J. Thomas Grayston
Vice President for Health Sciences
University of Washington
Seattle, Washington

Dr. Severo Ochoa
Distinguished Member
Roche Institute of Molecular Biology
Nutley, New Jersey

Dr. George E. Palade
Sterling Professor of Cell Biology
School of Medicine
Yale University
New Haven, Connecticut

Dr. David B. Skinner
Dallas B. Phemister
Professor of Surgery
Chairman, Department of Surgery
University of Chicago
Chicago, Illinois

Dr. Howard Temin
Professor of Oncology
McArdle Laboratory for Cancer Research
University of Wisconsin Medical Center
Madison, Wisconsin

Dr. Norman Wessells
Professor
Department of Biological Sciences
Stanford University
Stanford, California

Dr. Chien-Shiung Wu
Pupin Professor of Physics
Department of Physics
Columbia University
New York, New York

Fundamental Research

Executive Secretaries:

Dr. Vida Beaven
Special Assistant to the Deputy Director
National Institutes of Health

Dr. Michael Ebert
Chief, Section on Experimental Therapeutics
National Institute of Mental Health
Intramural Research Program
Alcohol, Drug Abuse, and
Mental Health Administration

Dr. Carl Leventhal
Deputy Director
National Institute of Arthritis,
Metabolism and Digestive Diseases
National Institutes of Health

Dr. Marvin Snyder
Special Assistant to the Deputy Director
Division of Research
National Institute on Drug Abuse
Alcohol, Drug Abuse, and Mental Health
Administration

PANEL 2

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

Chairperson:

Dr. Paul Marks
Vice President for Health Sciences
College of Physicians and Surgeons
Columbia University
New York, New York

Co-Chairpersons:

Dr. Barbara C. Hansen
Associate Dean for Graduate Studies
and Research
School of Nursing
University of Michigan
Ann Arbor, Michigan

Dr. Samuel O. Thier
Professor and Chairman
Department of Internal Medicine
School of Medicine
Yale University
New Haven, Connecticut

Dr. P. Roy Vagelos
President
Merck Sharp & Dohme Research
Laboratories Division
Merck & Company, Inc.
Rahway, New Jersey

Panel Members:

Dr. Charles G. Child III
Surgical Education Department
Tiedmont Hospital
Atlanta, Georgia

Dr. Robert B. Edmiston
Executive Vice-President-
Professional Affairs
Pennsylvania Blue Shield
Camp Hill, Pennsylvania

Dr. Henry W. Foster, Jr.
Professor and Chairman
Department of Obstetrics
and Gynecology
Meharry Medical College
Nashville, Tennessee

Dr. Clifton R. Gaus
Director of Policy, Planning
and Research
Health Care Financing Administration
Washington, D.C.

Clinical Applications and Health Services Research

Dr. Carl V. Granger
Director
Physical and Medical Rehabilitation
Memorial Hospital Family Care Center
Pawtucket, Rhode Island

Dr. Richard Hammond
Austell, Georgia

Dr. Kurt J. Isselbacher
Mallinckrodt Professor of Medicine
Harvard Medical School
Chief, Gastrointestinal Unit
Massachusetts General Hospital
Boston, Massachusetts

Dr. Saul Krugman
Professor of Pediatrics
School of Medicine
New York University
New York, New York

Dr. Robert Levy
Director
National Heart, Lung & Blood Institute
National Institutes of Health
Bethesda, Maryland

Dr. George I. Lythcott
Administrator
Health Services Administration
Rockville, Maryland

Dr. Franklin Mirer
Industrial Hygiene Consultant
Social Security Department
International Union
United Automobile Workers
Detroit, Michigan

Dr. Robert C. Orr
Clinical Assistant Professor
College of Osteopathic Medicine
Michigan State University
East Lansing, Michigan

Mrs. Dorothy P. Rice
Director
National Center for Health Statistics
Public Health Service
Washington, D.C.

Clinical Applications and Health Services Research

Dr. Donald C. Riedel
Professor and Chairman
Department of Health Services
School of Public Health
and Community Medicine
University of Washington
Seattle, Washington

Dr. Gerald Rosenthal
Director, National Center for
Health Services Research
Hyattsville, Maryland

Dr. David C. Sabiston, Jr.
Professor of Surgery
Chairman, Department of Surgery
Duke University Medical Center
Durham, North Carolina

Marilynn A. Schmidt, C.N.M., M.S.
Director
Nurse-Midwifery Educational Program
School of Nursing
Georgetown University
Washington, D.C.

Dr. Theodore R. Sherrod
Professor of Pharmacology
College of Medicine
University of Illinois
Chicago, Illinois

Dr. William S. Yamamoto
Chairman
Department of Clinical Engineering
George Washington Medical Center
Washington, D.C.

Executive Secretaries:

Dr. Samuel Korper
Senior Research Manager, GMENAC
Office of the Assistant Secretary
for Health

Dr. Ira Raskin
Director, Office of Program Development
National Center for Health Services
Research

Dr. Robert Ringler
Deputy Director
National Institute on Aging
National Institutes of Health

Clinical Applications and Health Services Research

Dr. Frank Sullivan
Executive Director
National Institute of Mental Health
Research Advisory Group
Alcohol, Drug Abuse, and
Mental Health Administration

PANEL 3

HEALTH REGULATION AND PROMOTION

Chairperson:

Dr. Leon Eisenberg
Presley Professor of Psychiatry
Harvard Medical School
Senior Associate in Psychiatry
Children's Hospital Medical Center
Boston, Massachusetts

Co-Chairperson:

Dr. Denise Kandel
Department of Psychiatry and
School of Public Health
Columbia University and
New York State Psychiatric Institute
New York, New York

Panel Members:

Dr. Eula Bingham
Assistant Secretary for Occupational
Safety and Health
Department of Labor
Washington, D.C.

Dr. Merle Bundy
Director of Industrial Medicine
U.S. Steel Corporation
Pittsburgh, Pennsylvania

Dr. John W. Bussman
Children's Clinic
Portland, Oregon

Mr. Douglas M. Costle
Administrator
Environmental Protection Agency
Washington, D.C.

Dr. Robert W. Day
Dean
School of Public Health
and Community Services
University of Washington
Seattle, Washington

Ngina Darden, R.N., M.S.W., M.P.H.
Los Angeles, California

Dr. Florence L. Denmark
Executive Officer
Department of Psychology
City University of New York
New York, New York

Health Regulation and Promotion

Dr. William H. Foege
Director
Center for Disease Control
Atlanta, Georgia

Dr. Sidney Katz
Professor and Chairman
Department of Community
Health Sciences
Michigan State University
East Lansing, Michigan

Mr. Donald W. Kemper
Executive Director
Healthwise Incorporated
Boise, Idaho

Dr. Marcus M. Key
Professor of Occupational Medicine
School of Public Health
Health Science Center
University of Texas
Houston, Texas

Ms. Francine Martin
Chief
Office of Health Education
Arizona Department of Health Services
Phoenix, Arizona

Dr. Kenneth L. Melmon
Chief
Division of Clinical Pharmacology
University of California
San Francisco, California

Dr. Norton Nelson
Professor and Chairman
Department of Environmental Medicine
Medical Center
New York University
New York, New York

Dr. Lloyd H. Rogler
Albert Schweitzer Professor
of Sociology
Director, Hispanic Research Center
Fordham University
Bronx, New York

Health Regulation and Promotion

Ms. Lisbeth Schorr
Consultant
Children's Defense Fund
Washington, D.C.

Dr. Carl M. Stevens
Professor of Economics
Reed College
Portland, Oregon

Mr. George H. R. Taylor
Director, Department of Occupational
Safety and Health and Environment
American Federation of Labor
and Congress of Industrial Organizations
Washington, D.C.

Dr. Barbara A. Underwood
Associate Professor of Nutrition
Department of Nutrition
and Food Science
Massachusetts Institute of Technology
Cambridge, Massachusetts

Dr. Carolyn A. Williams
Associate Professor of Nursing
Assistant Professor of Epidemiology
School of Public Health
University of North Carolina
Chapel Hill, North Carolina

Executive Secretaries:

Mr. Robert Frankel
Deputy Associate Director
for New Drug Evaluation
Bureau of Drugs
Food and Drug Administration

Dr. William Gay
Director
Extramural Activities Program
National Institute of Allergy
and Infectious Diseases
National Institutes of Health

PANEL 4

RESEARCH CAPABILITY

Chairperson:

Dr. William H. Danforth
Chancellor
Washington University
St. Louis, Missouri

Co-Chairperson:

Dr. Elizabeth Shull Russell
Senior Staff Scientist
Jackson Laboratory
Bar Harbor, Maine

Panel Members:

Dr. Robert A. Alberty
Dean
School of Science
Massachusetts Institute of Technology
Cambridge, Massachusetts

Dr. Jack Barchas
Department of Psychiatry
School of Medicine
Stanford University
Stanford, California

Dr. Marjorie Batey
Professor
Department of Community
Health Care Systems
School of Nursing
University of Washington
Seattle, Washington

Dr. Ivan Bennett
Provost and Dean
New York University
Medical Center
New York, New York

Dr. Eugene Cota-Robles
Professor of Biology
University of California at Santa Cruz
Santa Cruz, California

Dr. Clifton O. Dummett
Professor of Dentistry
University of Southern California
Los Angeles, California

Dr. Henry A. Foley
Administrator
Health Resources Administration
Hyattsville, Maryland

Research Capability

Dr. Robert Glaser
President
Henry J. Kaiser Family Foundation
Palo Alto, California

Dr. Maureen M. Henderson
Assistant Vice President for
Health Sciences
Health Sciences Center
University of Washington
Seattle, Washington

Mr. James F. Kelly
Executive Vice Chancellor
State University of New York
Albany, New York

Dr. Gerald L. Klerman
Administrator
Alcohol, Drug Abuse and
Mental Health Administration
Rockville, Maryland

Dr. Salvador Luria
Institute Professor Emeritus
Director for the Center for
Cancer Research
Massachusetts Institute of Technology
Cambridge, Massachusetts

Dr. Robert Q. Marston
President
University of Florida
Gainesville, Florida

Dr. William David McElroy
Chancellor
University of California
San Diego
La Jolla, California

Dr. Sherman M. Mellinkoff
Professor of Medicine and Dean
School of Medicine
University of California at Los Angeles
Los Angeles, California

Dr. John F. Sherman
Vice President
Association of American Medical Colleges
Washington, D.C.

Research Capability

Dr. Mildred Stahlman
Professor of Pediatrics
School of Medicine
Vanderbilt University
Nashville, Tennessee

Dr. Louis Sullivan
Dean and Director
School of Medicine
Morehouse College
Atlanta, Georgia

Executive Secretaries:

Dr. Doris Merritt
Special Assistant to the Director
National Institutes of Health

Dr. Jay Moskowitz
Director, Office of Program
Planning and Evaluation
National Heart, Lung, and Blood Institute
National Institutes of Health

PANEL 5

UNIFYING CONCEPTS

Chairperson:

Dr. John A. Gronvall
Dean
Medical School
University of Michigan
Ann Arbor, Michigan

(Substituting for:
Dr. Lewis Thomas
President
Memorial Sloan-Kettering
Cancer Center
New York, New York)

Co-Chairperson:

Dr. LeRoy B. Walters
Director, Center for Bioethics
Kennedy Institute
Georgetown University
Washington, D.C.

Panel Members:

Dr. Marcus Alexis
Professor
Economics and Urban Affairs
Chairman, Department of Economics
Northwestern University
Evanston, Illinois

Dr. Richard Atkinson
Director
National Science Foundation
Washington, D.C.

The Honorable David L. Bazelon
Circuit Judge
U.S. Court of Appeals
Washington, D.C.

Dr. Baruj Benacerraf
Chairman
Department of Pathology
Harvard Medical School
Boston, Massachusetts

Mr. Roger B. Dworkin
Professor of Law
School of Law
University of Virginia
Charlottesville, Virginia

Unifying Concepts

Mrs. Ruth Hanft
Deputy Assistant Secretary for Health
Policy, Research, and Statistics
Public Health Service
Washington, D.C.

Dr. T. C. Hsu
Professor of Biology
M.D. Anderson Hospital
and Tumor Institute
University of Texas
Houston, Texas

Dr. Ada Jacox
Associate Dean for Research
and Doctoral Program Development
School of Nursing
University of Colorado
Denver, Colorado

Dr. Donald Kennedy
Commissioner
Food and Drug Administration
Rockville, Maryland

Dr. Ruth Kirschstein
Director
National Institute of
General Medical Sciences
National Institutes of Health
Bethesda, Maryland

Dr. Richard M. Krause
Director
National Institute of Allergy
and Infectious Diseases
National Institutes of Health
Bethesda, Maryland

Dr. Frank Press
Director
Office of Science and Technology Policy
Executive Office of the President
Washington, D.C.

Dr. Eleanor B. Sheldon
President
Social Science Research Council
New York, New York

Unifying Concepts

Dr. Jeanne Sinkford
Dean, College of Dentistry
Howard University
Washington, D.C.

Dr. Charles Z. Wilson
Vice Chancellor
Academic Program
University of California
Los Angeles, California

Executive Secretaries:

Dr. Paul Parkman
Deputy Director
Bureau of Biologics
Food and Drug Administration

Dr. Seymour Perry
Associate Director for Medical
Applications of Research
National Institutes of Health



THE SECRETARY OF HEALTH, EDUCATION AND WELFARE
WASHINGTON, D.C. 20460

SAMPLE LETTER OF INVITATION
SENT TO NON-FEDERAL PANEL
MEMBERS

Dr. Samuel O. Thier
Professor and Chairman
Department of Medicine
School of Medicine
Yale University
New Haven, Connecticut 06510

Dear Dr. Thier:

The President's personal interest in Federal support for research and my own experience as Secretary of HEW have led me to initiate a new, open process to develop principles of a multi-year strategy to guide HEW health research activities. As part of this process, a National Conference on Health Research Principles will be held on October 3-4, at the National Institutes of Health in Bethesda, Maryland. The Conference will be structured around five major foci; five panels will receive public testimony on these five foci and reach a consensus on the principles the Department should adopt to guide health research activities. I invite you to participate in the Conference as a member of the panel on Clinical Applications and Health Services Research.

I have enclosed a copy of the remarks I made to the Annual Meeting of the American Federation for Clinical Research where I first described this new process and my objectives and expectations for this initiative (Enclosure #1). Many of the health problems and controversies I have faced as Secretary of HEW stem from the dilemma created by competing needs and limited resources. In deciding how best to allocate limited resources for health research, it is essential that we consider the advice and views of people and organizations affected by our decisions.

A broad range of professional societies and health organizations have been asked for their suggestions on the principles the Department should adopt. Other Federal Departments and agencies have been asked for their ideas and advice. The comments received from the health community, the public, and other Federal agencies are now being considered in formulating a statement of proposed HEW health research principles to be presented to the National Conference.

All agencies engaging in health research within the Department, the Office of the Assistant Secretary for Health, and other staff offices are involved in this effort. A statement which suggests health research principles for HEW is now being developed based on agency and staff office proposals and consideration of public comments. The proposed DHEW statement of principles will consolidate agencies' views where appropriate and identify alternatives where consensus is not achieved.

Page 2 - Dr. Samuel O. Thier

This statement will be organized around the five major foci which will also provide the substantive framework for the Conference. A description of these foci is provided in Enclosure #2. The proposed statement of HEW health research principles and a summary of public comments will be sent to all Conference participants in mid-September.

The National Conference will serve both as a forum to elicit additional public advice and to reach consensus on the principles the Department should adopt. The Conference will be structured to provide maximum opportunity for public input. The Conference structure is described in Enclosure #3. A memorandum recently has been sent to approximately 1,000 professional societies and health organizations outlining the Conference plans and inviting their representatives or members to attend the Conference as public witnesses.

The five panels will be responsible for receiving public testimony from preregistered witnesses and for revising and refining the proposed HEW statement of health research principles based on a consideration of oral and written public testimony. Each panel will consist of approximately 20 members and include representatives of the health research community, public interest and user groups, and private industry as well as members of the Federal Government. A listing of the composition of the panels will be sent to you shortly.

The two-day Conference will be intensive and may impose heavy demands on the panel members. The Conference will result in a draft report of health research principles for the Department. This report will also be distributed widely for public comment and will form the basis for the later development of a multi-year strategy for health research in the Department. Plans are now being formulated for these post-Conference activities.

I have asked Dr. Donald Fredrickson, Director of the National Institutes of Health, to serve as the focal point in moving this effort forward and to provide you with any additional information you may require. Information on your honorarium and expenses is provided in Enclosure #4.

This is a unique and critically important effort. Your participation will contribute significantly to the success of this enterprise and in the shaping of Department health research activities in the years ahead.

Sincerely,

Joseph A. Califano, Jr.

Enclosures

(Not Included)

SAMPLE LETTER OF INVITATION
SENT TO HEW PANEL MEMBERS

Dr. Ruth Kirschstein
Director
National Institute of
General Medical Sciences
National Institutes of Health
Building 31, Room 4A52
Bethesda, Maryland 20014

Dear Dr. Kirschstein:

As you know, as part of the new, open process to develop principles of a multi-year strategy to guide HEW health research activities, the National Conference on Health Research Principles will be held on October 3-4, at the National Institutes of Health. I ask that you participate in the Conference as a member of the panel on Unifying Concepts.

The National Conference will serve both as a forum to elicit public advice and to reach consensus on the principles the Department should adopt. The Conference will be structured around five major foci -- Fundamental Research, Clinical Applications and Health Services Research, Health Regulation and Promotion, Research Capability, and Unifying Concepts. Five panels are being established to address these five foci which also provide the substantive framework for the proposed statement of HEW health research principles.

A memorandum recently has been sent to approximately 1,000 professional societies and health organizations outlining the Conference plans and inviting their representatives or members to attend the Conference as public witnesses. The proposed statement of HEW health research principles and summaries of comments received from the public and other Federal agencies will be sent to all Conference participants in mid-September.

The five panels will be responsible for receiving public testimony from preregistered witnesses and for revising and refining the proposed HEW statement of health research principles based on a consideration of oral and written public testimony. Each panel will consist of approximately 20 members and include representatives of the health research community, public interest and user groups, and private industry as well as other members of the Federal Government.

The two-day Conference will be intensive. The Conference will begin at 9:00 a.m. on October 3rd, and end at approximately 5:00 p.m. on October 4th. There will be panel working sessions during the evening of October 3rd. Information on the Conference arrangements is enclosed.

Page 2 - Dr. Ruth Kirschstein

As you know, Don Fredrickson is serving as the focal point in moving this effort forward. He will be contacting you shortly and will provide any additional information you may require.

I recognize that the timing of this Conference is short and will impose additional demands on your busy schedule. However, your continued participation will contribute significantly to the success of this important Department initiative.

Sincerely,

Joseph A. Califano, Jr.

Enclosure (Not Included)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

SAMPLE
AND WELFARE

September 15, 1978

Dr. Donald W. Seldin
Professor and Chairman
Department of Medicine
Southwestern Medical School
University of Texas
5323 Harry Hines Boulevard
Dallas, Texas 75235

Dear Don:

Secretary Califano has asked me to convey to you his appreciation for your willingness to serve as a Panel Chairperson at the National Conference on Health Research Principles. I also would like to thank you, recognizing that the timing of the Conference has imposed hardships upon you in rearranging your busy schedule. As you know, the Conference will be held on October 3-4 at the National Institutes of Health in Bethesda, Maryland and an orientation session for you and the other Panel Chairpersons and Co-Chairpersons has been scheduled for 8:00 p.m., October 2, at the Linden Room, Linden Hill Hotel in Bethesda. A special briefing has been arranged for those unable to attend this session. This briefing will be held in my office (Room 124, Building 1) at 8:00 a.m. on Tuesday, October 3rd.

Secretary Califano will be in touch with you shortly to indicate how the Conference results will be used in the DHEW five-year planning and budgetary processes and how your recommendations will influence the allocation of limited resources and the manner in which the Department is organized to carry out health research activities. You have received a brief description of the Conference objectives, structure and general operation from Kurt Habel or Nancy Braymer of the NIH Program Planning staff. Additional information is provided in the enclosed memorandum and attachments which are being sent to all individuals who have registered for the Conference.

Attachment #1 contains the Conference program and the membership of each Panel. After the brief opening plenary session on Tuesday morning, October 3rd, each Panel will receive public testimony for the rest of the day from pre-registered witnesses. The number of witnesses expected to testify before each Panel is shown in the enclosed memorandum. Due to the large number of witnesses registered to testify before the Fundamental Research and Clinical Applications and Health Services Research Panels, these Panels must be split Tuesday morning and afternoon to receive testimony. These Panels will remain split for a short period of time after dinner on October 3rd to summarize, then reconvene as single, full Panels that evening in conference rooms 6 (Fundamental Research) and 10 (Clinical Applications and Health Services Research) in Building 31.

All testimony before each Panel must be held to five minutes. Registered participants have been informed of this limitation and will have an opportunity to extend their remarks by submitting written comments after the Conference. Panel Chairpersons will be responsible for invoking the five minute limitation and ensuring that all those who have registered to testify have an opportunity to be heard. The testimony schedule, listing witnesses who will appear before you, will be given to you at the orientation session.

Since October 3rd is a holiday observed by many, those unable to participate on Tuesday will be provided an opportunity to present testimony on Wednesday morning. Panel members arriving Wednesday morning due to holiday observances will be provided a briefing prior to the morning's session.

Tuesday evening and most of Wednesday morning will be devoted to working sessions at which each Panel will develop a draft report which addresses health research principles in its individual substantive area. The Panel Chairperson will present the report and summarize the Panel's findings at the closing plenary session on Wednesday afternoon.

Attachments #2, 3, and 4 provide much of the material to be considered in developing the Panel reports. In addition, at the orientation session you will receive an indexed copy of all suggestions on which the summary of public comment contained in Attachment #3 is based and a copy of written testimony submitted by individuals and organizations unable to attend the Conference but who wish the Panels to consider their views.

The draft Panel reports should be based upon the attachments, the materials distributed at the Conference, the testimony of public witnesses, and the Panel's expertise in the substantive area. The draft reports may consist of revisions to the draft Department principles in Attachment #2 or may represent entirely new documents. The most effective approach will remain the option of each Panel. However, it is essential that the draft reports reflect the fact that resources are limited and that choices must be made among competing needs. A sample format for you to consider in drafting the individual Panel reports will be available for discussion at the orientation session.

After the Conference an integrated draft report of health research principles for the Department will be prepared. This will be forwarded to you for your review. The draft report subsequently will be distributed widely for public comment.

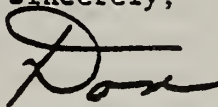
Each Panel will be supported by an Executive Secretary and a stenographer. The Executive Secretary's role will be to summarize oral and written testimony received and work with the Panel in developing the draft report. The Executive Secretaries will also be at the orientation

session Monday evening. Please note that Attachment #5 provides additional logistical information, including maps of the locations of all Panel sessions and procedures for the operation of the two split Panels. At the opening and closing plenary sessions, I would like you to be seated on the stage at the Masur Auditorium. Also, although it will be necessary for Panel members to register at a special desk adjacent to the Auditorium before the opening plenary session, this will be taken care of for you at the orientation session. A list of the material which will be distributed and discussed at the orientation session is attached.

On behalf of the Institute of Medicine, National Academy of Sciences, Dr. David Hamburg, the Institute's President, has accepted an invitation from Secretary Califano to provide an independent evaluation of the draft Conference report. An Institute of Medicine committee has been appointed for this purpose, and members of this committee will attend the Conference.

I look forward to seeing you at the Conference. Your participation as Chairperson of the Fundamental Research Panel will contribute significantly to this effort. If you have any questions or need additional information, please let Kurt Habel or Nancy Braymer know (telephone 301/496-1454).

Sincerely,

A handwritten signature in dark ink, appearing to read "Don", with a stylized flourish extending from the end.

Donald S. Fredrickson, M.D.
Director

Enclosures (Not Included)



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

SAMPLE

NATIONAL INSTITUTES OF HEALTH

BETHESDA, MARYLAND 20014

September 15, 1978

Floyd Elliott Bloom, M.D.
Director
Arthur V. Davis Center for
Behavioral Neurobiology
Salk Institute
P.O. Box 1809
San Diego, California 92112

Dear Dr. Bloom:

Joseph A. Califano, Jr., the Secretary of the Department of Health, Education, and Welfare has asked that I convey to you his appreciation for your willingness to serve as a Panel member at the National Conference on Health Research Principles. I also would like to add my personal expression of appreciation, with the full recognition that the timing of the Conference has imposed hardships upon you in rearranging your busy schedule. As you know, the Conference will be held on October 3-4 at the National Institutes of Health in Bethesda, Maryland.

You have received a brief description of the Conference objectives, structure and general operation from Kurt Habel or Nancy Braymer of the NIH Program Planning staff. Additional information is provided in the enclosed memorandum and attachments which are being sent to all individuals who have registered for the Conference.

Attachment #1 contains the Conference program and the membership of each Panel. After the brief opening plenary session on Tuesday morning, October 3rd, each Panel will receive public testimony for the rest of the day from pre-registered witnesses. The number of witnesses expected to testify before each Panel is shown in the enclosed memorandum. The testimony schedule, listing witnesses who will appear before you, will be given to you at the registration desk Tuesday morning. Due to the large number of witnesses registered to testify before the Fundamental Research and Clinical Applications and Health Services Research Panels, these Panels must be split Tuesday morning and afternoon to receive testimony.

Since October 3rd is a holiday observed by many, those unable to participate on Tuesday will be provided an opportunity to present testimony on Wednesday morning. Tuesday evening and most of Wednesday morning will be devoted to working sessions at which each Panel will develop a draft report which addresses health research principles in its individual substantive area. The Panel Chairperson will present the report and summarize the Panel's findings at the closing plenary session on Wednesday afternoon.

Attachments #2, 3, and 4 provide much of the material to be considered in developing the Panel reports. In addition, at the Conference you will receive an indexed copy of all suggestions on which the summary of public

comment contained in Attachment #3 is based and a copy of written testimony submitted by individuals and organizations unable to attend the Conference but who wish the Panels to consider their views. The draft Panel reports should be based upon the attachments, the materials distributed at the Conference, the testimony of public witnesses, and the Panel's expertise in the substantive area. The draft reports may consist of revisions to the draft Department principles in Attachment #2 or may represent entirely new documents. The most effective approach will remain the option of each Panel. After the Conference an integrated draft report of health research principles for the Department will be prepared. This will be forwarded to you for review and comment. The draft report subsequently will be distributed widely for public comment.

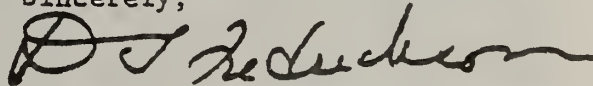
On behalf of the Institute of Medicine, National Academy of Sciences, Dr. David Hamburg, the Institute's President, has accepted an invitation from Secretary Califano to provide an independent evaluation of the draft Conference report. An Institute of Medicine committee has been appointed for this purpose, and members of this committee will attend the Conference.

Each Panel will be supported by an Executive Secretary and a stenographer. The Executive Secretary's role will be to summarize oral and written testimony received and work with the Panel in developing the draft report. Detailed logistical arrangements, suggested procedural rules, and sample report formats will be provided to each Panel Chairperson, Co-Chairperson and Executive Secretary prior to the Conference.

A seat at both plenary sessions has been reserved for you. However, it will be necessary for you to register before the opening plenary session begins at 9:00 a.m. A special desk for registration of Panel members will be located in the lobby of the Masur Auditorium, Building 10 (Clinical Center). At that time, you will be given a complete roster of Panel membership, including the composition of the two Panels which must be split on Tuesday morning and afternoon. Attachment #5 provides additional logistical information, including maps of the locations of all Panel sessions and procedures for the operation of the two split Panels.

I look forward to seeing you at the Conference. Your participation will contribute significantly to this effort. If you have any questions or need additional information, please let Kurt Habel or Nancy Braymer know (telephone 301/496-1454).

Sincerely,



Donald S. Fredrickson, M.D.

Director



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

JUL 9 1978

MEMORANDUM TO: Panel Chairmen and Members

SUBJECT : Goals of the National Conference on Health
Research Principles

I appreciate your willingness to participate in the National Conference on Health Research Principles.

You have already received the draft principles prepared by various agencies in HEW as well as the other documents prepared for review prior to the Conference. I thought it might be helpful if I also explained how we hope to use the results of the Conference to develop a health research strategy for the Department of Health, Education, and Welfare, and what I believe your role in these activities might be.

The draft principles that were sent to you reflect the suggestions received over a number of months from many individuals, agencies and organizations whose views I solicited. In their present form, the draft principles also reflect major efforts by the NIH and HEW staffs to analyze, synthesize, and organize these views and comments. I have examined these principles with some care. In my view, these principles--when reviewed and further refined by panel members like you--should provide an excellent beginning point for developing the goals that can result in a five-year health research strategy and budget for the Department by the fall of 1979. In a real sense, you must be my eyes and ears at the Conference, carefully reviewing and responding to the public comment and resynthesizing the preliminary principles you have before you.

In reviewing and rewriting these principles, I ask you to keep clearly in mind their ultimate purpose: to form the basis for deciding the direction that HEW's research efforts should follow in the next few years. The set of principles developed, at this Conference, will form the basis for selecting specific goals for health research and for establishing clear budget targets over the next five years for reaching these goals. As I see it, the goals that emerge might very well result in changes to the organization and missions of present health agencies, with significant impact also on the development of agency budgets over the next five years. I have asked the HEW Steering Committee

that will oversee this process to develop both the goals and a five-year research budget by the fall of 1979.

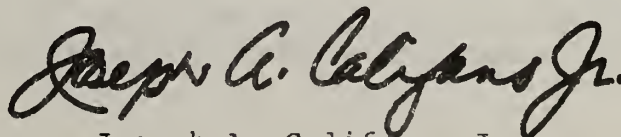
The process of developing a strategy to reach the goals selected and budgetary targets will begin once the principles have been reported from the Conference. We will, of course, provide further opportunity for comment by you and others--as well as for an independent critique by the Institute of Medicine--as we proceed.

If we are to press ahead quickly to develop the five-year strategy and budget by the fall of 1979, it is extremely important that you attempt to shape the development of principles to the assigned focus of your panel, and to attempt to make those principles form the basis for specific goals.

In setting goals, we must recognize the unfortunate but nevertheless real limitations on resources for health research that we now face. As you know, President Carter is determined to assure adequate funding for basic research and not to seek false economies by cutting research expenditures. But we cannot ignore the constraints we face. Every day brings more forcibly to us in Government the painful limits on available resources. Thus, I understand, and strongly support, the long term investments in basic research that we must continue to make as the sine qua non in our search for improved health. But not all areas of basic research--not even all promising areas--can be explored at once or with equal energy.

Similarly, as we move toward the applied or developmental end of the health research spectrum, we face a tremendous need for research that seeks solutions to the great range of health problems that concern the public and the Congress. Yet here, too, we must be selective. We cannot do everything at once. Neither can we simply propose new or greatly expanded initiatives requiring large increases in Federal support. Rather, we must make the best use of what we now have in hand. But to do this, we will have to choose wisely and with foresight. It is here that we will need all the help we can get from you.

I look forward to receiving your reports, and I thank you in advance for your efforts in making the Conference a success.

A handwritten signature in dark ink, reading "Joseph A. Califano, Jr.", with a stylized, cursive script.

Joseph A. Califano, Jr.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

December 18, 1978

MEMORANDUM TO: Panel Chairmen and Members

SUBJECT: Report on the National Conference on Health Research
Principles

I was pleased to receive your Panel Reports, and on behalf of Secretary Califano and myself I thank you for your efforts in making the National Conference a success. Your contributions have moved us closer to the adoption of a set of health research principles for the Department of Health, Education, and Welfare to guide the development of a multi-year research strategy. I congratulate each of you on this report and look forward to your continued participation in this activity.

In my view, these principles, when reviewed and further refined, should provide a starting point for developing the goals that can result in a five-year health research strategy and budget for the Department by the fall of 1979. Your comments on the enclosed report, coupled with the results of the evaluation of this report by the Institute of Medicine, National Academy of Sciences, will form the basis for the completion of this phase of the initiative; namely, the establishment of health research principles for DHEW.

The next step in this initiative will be to spell out specific health research goals based upon the principles finally adopted. Once these goals have been identified, the task will be to translate them into a plan and budget by the Fall of 1979.

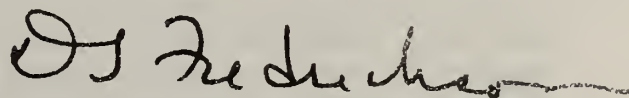
While the revised research principles enclosed are still subject to possible changes, they do at least provide a reasonable starting point for efforts to translate research principles into research goals. Therefore, if you would be willing to include suggestions for goals with your comments to me in revised principles, this would be most helpful.

Documents relating to the development of the draft principles beginning with the Secretary's address before the Annual Meeting of the American

Page 2

Federation for Clinical Research in April and extending through those for the National Conference will be published soon as the public record for this initiative. As soon as this publication is ready, I will have it sent to you.

Once again, I thank you for your efforts and look forward to your comments on the Conference Report. Please send your comments to me by February 1, 1979.

A handwritten signature in dark ink, appearing to read "D S Fredrickson", with a long horizontal flourish extending to the right.

Donald S. Fredrickson, M.D.
Director

Enclosure



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

JUL 19 1978

MEMORANDUM TO: Professional Societies and Health Organizations

SUBJECT: HEW Multi-Year Strategy for Support for Health Research

The future of Federal support for health research is a subject of intense interest and importance.

Last July, President Carter ordered a comprehensive review of Federal support for basic research. Based on this review, the President directed that a new emphasis be placed on research in Federally supported science programs.

During the time I have been Secretary, I have learned that at the core of many health problems and controversies that government must resolve is the dilemma created by enormous and pressing needs on the one hand and limited resources on the other. Indeed, in no other field is that dilemma more sharply posed -- or more important to resolve -- wisely and fairly -- than in health and health research.

The Federal government has become the dominant force in biomedical research not only in this country, but increasingly, throughout the world. It supports the largest health research establishment in the world today. HEW's support for health research amounted to an estimated \$3.4 billion in 1977 -- over 60 percent of the nation's total expenditure for such research and almost 80 percent of the Federal health research effort.

The National Institutes of Health today oversee a research budget of \$2.7 billion in support of 15,000 principal investigators including 13,000 research grantees in non-Federal institutions.

As Secretary of HEW, I have begun an important new process to develop, for the first time, a multi-year strategy to guide the allocation of limited government health research dollars.

Page 2

It is critical that the principles we develop take into account the views, perspectives, and concerns of people and organizations affected by our decisions. I ask that you send me your views and suggestions -- by August 7, if at all possible -- on the principles that the Department should adopt to guide these hard choices. I have enclosed a copy of the remarks I made to the Annual Meeting of the American Federation for Clinical Research on this subject, which will provide some background on our current thinking.

Once we have considered your advice, we will develop a set of proposed principles to be presented to a National Conference on October 3-4, 1978, to be held at the National Institutes of Health. If you wish, a copy of the proposed principles will be sent to you before the conference for your review.

I have asked Dr. Donald Fredrickson, Director of the National Institutes of Health, to serve as the focal point in moving this effort forward and in planning the national conference. All agencies engaging in health research within the Department, and the Office of the Assistant Secretary for Health, will be actively involved in this effort. Dr. Fredrickson will be pleased to provide you with additional information if you desire.

I attach great importance to this effort. The process we are embarking upon will be critical to the development of a strategy to guide health research activities in the Department and in the Nation in the years ahead. I hope you will help us in this effort by providing us your thoughts and suggestions.


Joseph A. Califano, Jr.

Enclosure

Addresses are listed in Appendix A



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

August 11, 1978

MEMORANDUM TO: Professional Societies and Health Organizations

SUBJECT: Plans for National Conference on Health Research Principles

Joseph A. Califano, Jr., the Secretary of the Department of Health, Education, and Welfare, has asked that I keep you informed of plans for the National Conference on Health Research Principles and invite you to participate in the two day proceedings. The Secretary has recently asked for your suggestions to assist him in developing health research principles for the DHEW and has indicated that the Conference will be held at the National Institutes of Health in Bethesda, Maryland, on October 3-4. On behalf of Secretary Califano, I would like to invite you or representatives from your organization to attend the Conference as public witnesses. Both the Secretary and I believe your contributions to this important DHEW initiative will be quite helpful.

Suggestions received early in this process have contributed greatly to the planning of the Conference. The following attachments will give you an idea of the planning to date:

- Attachment #1 - Conference Structure
- Attachment #2 - Major Foci of the Conference
- Attachment #3 - Composition of Conference Panels
- Attachment #4 - Conference Registration Form - Please note the return date of September 1, if you wish to register for the Conference.
- Attachment #5 - Hotel Information (Not Included)

If you wish to register for the Conference or provide written comments to be considered during the Conference, and so indicate on the registration form, certain pre-Conference material will be sent to you during mid-September. This will include:

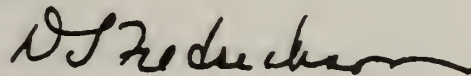
- Detailed information on the administrative and logistical management of the Conference,
- A finalized agenda with detailed scheduling of public testimony before each panel,

- A proposed statement of DHEW health research principles, organized around the five major Conference foci.
- A summary of all public comments for principles suggested for consideration which are received prior to the Conference, organized around the five major Conference foci. A broad community of professional societies and health organizations have been invited by Secretary Califano to provide suggestions and have been invited to participate, as public witnesses, in the Conference.

The Conference will result in a draft report of health research principles for the Department. This report will also be distributed widely for public comment and will form the basis for the later development of a multi-year strategy for health research in the Department.

The number of individuals who can be accommodated at the two plenary sessions of the Conference will be limited to about 500, due to the size of the facilities. Attendance at the plenary sessions will be determined by the return date of your registration form. Each attendee must submit a separate registration form, so please copy attachment #4 if necessary. The working panel sessions will form the bulk of the Conference; plenary sessions will be as brief as possible. The working panel sessions will be structured to allow for all who wish to speak to do so. Public testimony before the working panel sessions will be brief (10 minutes or less) and will be determined after registration forms are received. These sessions will be held in conference rooms accommodating 100-225. All participants will be expected to provide a copy of their testimony to the working panel at the time of their presentation and will also be expected to make their own travel and hotel arrangements. Your testimony should be structured around the Conference foci (Attachment #2) and the pre-Conference materials which will be mailed to you.

Since the time for planning this Conference is short, I urge you to forward this invitation to appropriate members of your organization immediately. Once again, Secretary Califano and I look forward to your possible participation in the Conference and suggestions you may have.



Donald S. Fredrickson, M.D.
Director

Enclosures

ATTACHMENT #1

CONFERENCE STRUCTURE

October 3-4, 1978

National Institutes of Health

Bethesda, Maryland

First Day - October 3, 1978

Morning: Plenary Session

Opening Remarks and Charge to Panel Members:

- The Secretary of Health, Education, and Welfare
- The Assistant Secretary for Health
- The Director, National Institutes of Health

Late Morning

Through Afternoon: Panel Sessions -- Public Testimony

The Conference will divide into five separate panels structured around five major foci and receive public testimony from pre-registered witnesses. Testimony will be based upon the proposed statement of HEW health research principles. Witnesses will receive a copy of the proposed HEW principles and a short summary of prior public comments at least two weeks before the Conference and will be asked to submit a written statement of their remarks for the panels' use.

Evening: Panel Working Sessions

Panels will revise and refine the draft principles which relate to their foci based on the public testimony and prepare preliminary reports.

Second Day -- October 4, 1978

Morning: Panel Working Sessions

The panels will meet separately to review, discuss, and revise their preliminary reports.

Afternoon: Plenary Session

The panels would reconvene and present their reports.

ATTACHMENT #2

MAJOR FOCI OF THE CONFERENCE

Five major foci will serve as the substantive framework for the Conference. The first three foci address segments of the health research continuum and together provide a structure to consider the health research activities of all Department health agencies and the knowledge base for all Department health missions; the fourth addresses resources for research (institutional, manpower, facilities and equipment) and the fifth will serve as an integrating force to bridge and relate the others. The major foci are:

- FUNDAMENTAL RESEARCH -- This focus will address the need for fundamental research (the search for knowledge about fundamental processes of biology and behavior), the creative process which governs this type of research activity, and its role in improving the health of the public and contributing the essential knowledge base on which other Department health missions rely. This area will also encompass the issue of stability of support and the relationship of fundamental research to other segments of the health research continuum.
- CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH -- This focus will address the development of the knowledge base to support the health care function, the need to acquire, validate and apply new knowledge, the characteristics and requirement for applied, problem-oriented research, and the need to retain and strengthen the Department's pluralistic approach in support of applied research.
- HEALTH REGULATION AND PROMOTION -- This focus will address the further development of the knowledge base necessary for regulatory decisions and preventive and control measures, the requirement to communicate effectively the nature and inherent constraints of the regulatory process, and the need to explore more structured and creative interactions between the health research agencies and the agencies responsible for health promotion and regulatory activities.
- RESEARCH CAPABILITY -- This focus will explore the issues involved in assuring that the resources, both physical and human, necessary for the conduct of research are available.

- UNIFYING CONCEPTS -- This focus will explore concepts which provide the philosophic base for public funding of health research and the interactions among the different parts of the research continuum necessary to move from the development of new knowledge to the application of research findings. Included will be consideration of the need to reaffirm the Federal support of health research, what the public should expect as a return on its investment in health research, how to communicate effectively the nature of the scientific process, its limitations and benefits, bridges between fundamental and applied research, and new interactions and processes to be explored.

ATTACHMENT #3

COMPOSITION OF CONFERENCE PANELS

Five panels to address and receive public testimony on the five major Conference foci will be established. Each panel will consist of 15 members. Based upon recommendations from all Department health agencies involved in this initiative, the Secretary, DHEW, will select the panel members.

The composition of each panel will be as follows:

Chairpersons - The panel chairpersons will be individuals widely recognized in the substantive area to be addressed under each foci.

Membership - Panel membership will be heavily drawn from outside the Federal Government and will include leading members of the health research community, public interest and user groups, and private industry.

- Panel membership will also include members of the Federal Government, drawn from DHEW agencies directly involved in this initiative, as well as from other parts of Government.

ATTACHMENT # 4

Pre-Registration Form
CONFERENCE ON HEALTH RESEARCH PRINCIPLES
October 3 and 4, 1978
National Institutes of Health, Bethesda, MD 20014

NAME	TITLE	
INSTITUTIONAL AFFILIATION		
MAILING ADDRESS		
CITY	STATE	ZIP

I plan to attend the conference: Yes ☐ No ☐

I plan to attend the Opening Plenary Session ☐ Closing Plenary Session ☐.

I plan to give public testimony at the following panel session(s):

- | | |
|---|--|
| ☐ Fundamental Research; | ☐ Health Regulation and Promotion; |
| ☐ Clinical Applications and
Health Services Research; | ☐ Research Capability;
☐ Unifying Concepts. |

I do not plan to attend the conference, but will submit comments to be considered. ☐

Because of the number of speakers to be accommodated, public testimony is limited to 10 minutes or less per person at each session.

A typed copy of your public testimony must be presented to conference officials at time of presentation.

Please return pre-registration form to NIH by **September 1, 1978.**



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

September 15, 1978

MEMORANDUM TO: Registered Participants

SUBJECT: National Conference on Health Research Principles

Joseph A. Califano, Jr., the Secretary of the Department of Health, Education, and Welfare, has asked that I convey to you his appreciation for your interest in the National Conference on Health Research Principles to be held on October 3-4 at the National Institutes of Health in Bethesda, Maryland. We look forward to your contributions and participation.

Plans for the Conference are described in the following attachments:

- Attachment #1 - Conference Program and Composition of Conference Panels
- Attachment #2 - Draft DHEW Health Research Principles
- Attachment #3 - Summary of General Themes of Public Suggestions for DHEW Health Research Principles
- Attachment #4 - Summary of Comments from Other Federal Departments and Agencies
- Attachment #5 - Conference Logistics and Administrative Information

The program in Attachment #1 indicates the location of each Conference session. Please note that due to the large number of witnesses who have pre-registered to testify before the Fundamental Research and Clinical Applications and Health Services Research Panels, these Panels must be split the morning and afternoon of October 3rd to receive testimony. There will be additions to the roster of Panel membership shown in Attachment #1. A complete roster, including the composition of the two Panels which must be split, will be available at the Conference.

Attachments #2, 3, and 4 provide the substantive documents for the Conference and should serve as a guide for the preparation of testimony before each Panel. In addition, at the Conference you will receive an indexed copy of all suggestions on which the summary of public comments in Attachment #3 is based.

All testimony before each Panel must be held to five minutes. This limitation is necessary to ensure that all individuals who have registered to testify will be heard, to provide an opportunity for questions by the Panel members, and to enable the Panels to complete their work. The numbers of individuals who have pre-registered to testify before each Panel is as follows:

- Fundamental Research - 70 witnesses
- Clinical Applications and Health Services Research - 70 witnesses
- Health Regulation and Promotion - 30 witnesses
- Research Capability - 40 witnesses
- Unifying Concepts - 40 witnesses

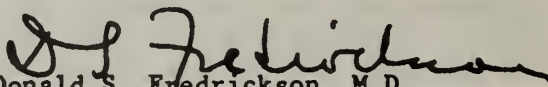
Witnesses will have an opportunity to extend their remarks by submitting written comments which will be incorporated in the Conference proceedings. The public record will be open two weeks after the Conference for this purpose. As Tuesday, October 3rd is a holiday observed by many, provision has been made to receive public testimony on Wednesday morning from witnesses unable to appear on Tuesday.

Attachment #5 provides the logistical and administrative information for the Conference. Please read this information carefully. The Conference logistics are complex and must be followed in the interests of all participants. Please note that it will be necessary for you to register before the opening plenary session begins at 9:00 a.m. on Tuesday.

Each Panel will develop a draft report for presentation at the closing plenary session on October 4th. The reports will be derived from the substantive Conference documents (Attachments #2, 3, and 4), the public testimony received, written testimony submitted by those unable to attend the Conference, and the knowledge brought to these proceedings by all of the individual Panel members. Once an integrated draft Conference report is prepared, it will be sent to all Conference participants, all organizations that provided suggestions, and other interested parties for their review and comment. Suggestions received at this point will be thoroughly analyzed, summarized and used as the basis for presenting recommendations on DHEW health research principles to the Secretary, DHEW. This analysis will also be available to the public upon request.

On behalf of the Institute of Medicine, National Academy of Sciences, Dr. David Hamburg, the Institute's President, has accepted an invitation from Secretary Califano to provide an independent evaluation of the draft Conference report. An Institute of Medicine committee has been appointed for this purpose, and members of this committee will attend the Conference.

Once again, Secretary Califano and I look forward to your participation in the Conference and the contributions you will make in shaping DHEW health research principles. If you have any questions or would prefer, because of the holiday, to testify on the morning of October 4th, please call Kurt Habel or Nancy Braymer of the NIH Program Planning staff (telephone 301/496-1454).


Donald S. Fredrickson, M.D.
Director

Attachments

Several of the attachments are not reproduced here as they are included elsewhere in this Volume as follows:

- Attachment #1 - Conference Program - pages 91-97
Composition of Conference Panels - pages 260-276
- Attachment #2 - Draft DHEW Health Research Principles - pages 212-235
- Attachment #4 - Summary of Comments from Other Federal Departments and Agencies - pages 239-242

ATTACHMENT #3

SUMMARY OF GENERAL THEMES OF PUBLIC SUGGESTIONS FOR DHEW HEALTH RESEARCH PRINCIPLES

In July, approximately 1,000 professional societies and health organizations were asked for their views and suggestions on health research principles for the Department. Attached are a summary of the general themes suggested in the initial public comments received and a list of the organizations that provided comments. This summary reflects an effort to identify briefly for consideration at the National Conference general areas of concern common to a number of organizations submitting comments. It is not intended to serve as a comprehensive summary of all points of view expressed nor as a complete synthesis and analysis of the comments received. For this reason, copies of all individual comments will be distributed at the Conference to each participant for review.

Once the draft report from the National Conference is ready for distribution, it will be sent to all organizations and individuals who have provided initial suggestions, all Conference participants, and other interested parties for their review and comment. All suggestions received will be thoroughly analyzed, summarized and considered in formulating recommendations on DHEW health research principles to be presented to the Secretary, DHEW. This analysis will also be available to the public upon request.

This summary is organized around the five major foci which will serve as the substantive framework for the National Conference on Health Research Principles and which have been used in developing the draft DHEW Health Research Principles. As the Secretary's remarks to the Annual Meeting of the American Federation for Clinical Research provided the context for public comment, some latitude has been required to adapt suggestions to this structure.

FUNDAMENTAL RESEARCH

Major, recurring themes reflected in the public comments may be summarized as follows:

- There is a need for a renewed national commitment to basic biomedical and behavioral research. Public patronage of fundamental research represents an investment for the public good. The Federal government's primary but not exclusive role in supporting fundamental research is appropriate and should be affirmed.
- Fundamental research is the key to advances in maintaining health, preventing and treating disease, and alleviating human suffering and disability. It is the most cost/effective approach to attain health goals in the long run.

- Stability and predictability of funding are essential. Fundamental research is a long-range, multi-year undertaking requiring long-term commitments by individuals and institutions. Stable, long-term support must be assured.
- An adequate or increased level of Federal investment in fundamental research is required. The decline in Federal support in constant dollars should be reversed and lost impetus regained. Among the factors identified as contributing to the erosion of the support base for fundamental research were inflation, escalating administrative costs, increased sophistication of biomedical technology, and pressures for increased emphasis on targeted research.
- Scientific activities and opportunities in fundamental research develop from the creativity of the investigators; program management must recognize this and respect the requirement for freedom of scientific inquiry and flexibility. Support mechanisms, measures of productivity, and planning approaches must be adopted to and foster the creative process that governs fundamental research.
- Investigator-initiated research must continue to be emphasized in the conduct of fundamental research.
- Scientific opportunity and evaluation for scientific excellence must remain the criteria for research support; the peer review system is the most effective approach for achieving this evaluation.
- There must be diversity in the research supported. Greater recognition should be given to research in the behavioral, social, and population sciences, epidemiology and biostatistics.
- The following disciplines, research areas, and diseases were identified as meriting additional emphasis: anesthesiology, reproductive biology, psychiatry, immunology, physiology, pharmaceutical sciences, plant physiology, neurology, aging, vision, underlying mechanisms of disease, environmental health, nutrition, epilepsy, genetic disorders and defects, pediatric disorders, prematurity, child development, human reproduction, infectious diseases, cardiovascular diseases, tropical diseases, chronic diseases, narcolepsy and other sleep disorders, central nervous system regeneration, communicative disorders, learning disabilities, sexual behavior, retinitis pigmentosa, degenerative disease, pain, Huntington's Disease, amyotrophic lateral sclerosis, Tuberous Sclerosis, Down's Syndrome, and Gilles de la Tourette Syndrome.

CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH

Recurring themes in the public comments which may be summarized under this focus include the following:

- Research to apply knowledge to solve health problems and improve health status and care must be supported. The knowledge base necessary to carry out health care missions must be further developed through applied research.
- New knowledge and technology which have been validated in terms of efficacy and safety must be transferred and applied at the earliest possible time. Further research and evaluation are needed to determine the most efficient and effective methods of technology transfer.
- Large-scale development efforts, clinical trials, demonstration projects, and introduction and evaluation of new methods to deliver health care are complex and expensive undertakings. Expanded support for multi-year, high cost clinical applications and health services research activities should be in addition to, not in lieu of support for fundamental research.
- Among the factors which should be considered in supporting applied research are the current state of the art, economic feasibility, societal needs, scientific excellence, availability of investigators and institutions with requisite expertise, burden of illness measures, prospect for achievement, and alternative funding sources within the public and private sectors.
- Support for the application of proven new knowledge and technology is available from multiple sources; these contributions should be recognized and encouraged. Technology transfer should be a shared responsibility of a number of Federal agencies, the health research community, private organizations and industry.

Additional, specific suggestions included the following:

- Health care research activities should be evaluated for scientific content and validity by peer review or the technical consensus process, whichever is appropriate for a particular program.
- NIH should not serve as the primary agency for technology transfer.
- A fund for the support of technology transfer activities should be created and related to the health care budget. It should be administered by an agency responsible to the Assistant Secretary for Health assisted by an advisory council.

- The National Academy of Sciences could serve as an interdisciplinary focus to disseminate research advances to the health research community.
- Interdisciplinary reviews should be conducted to synthesize current knowledge; telephonic data banks should be made available.
- Descriptions of both completed and on-going research supported by Federal funds should be systematically compiled and disseminated.
- Areas and studies identified as meriting additional emphasis and support were: development of broad measures of health status, alternatives to institutionalization of chronic mental patients, validation of new technology through controlled clinical trials, cost and effectiveness of new methods of health care delivery, consumer satisfaction, alternative methods to disseminate research findings, baseline survey research in sociodemographic, sociopsychological, socio-cultural and intraethnic group characteristics of minorities, home health care, prepaid group practice health care delivery, cost-effectiveness of intensive care units, hypnosis, availability of blood resources, primary care specialties, nursing profession and practice, food sciences, demographic change, clinical, social-psychological, and technological needs associated with physical disability, relationship between health services delivery and local health departments, and improved service delivery programs for specific diseases and disabilities.

HEALTH REGULATION AND PROMOTION

Public comments which addressed this focus emphasized the following:

- Efforts should be made to better inform and educate the public about the application of knowledge gained through research in order to promote better health. Research is needed on how best to foster the concept of individual responsibility for health maintenance and how to encourage the public to adopt preventive measures and, when necessary, to alter behavior and life style to preserve health.
- High priority should be accorded to preventive medicine; a better balance should be sought between research in prevention of disease and disability as opposed to research directed at therapies.
- Increased interdisciplinary efforts are needed to stimulate new research ideas in the area of disease prevention.

- Areas and studies identified as meriting emphasis and support were: health-related effects of behavior, environmental and occupational health, holistic medicine, cost implications of preventive strategies, nutrition education, sex education for teenagers, psychosocial medicine, risk assessment of carcinogenicity to quantify risk/benefit of known carcinogens, development of behavior-oriented intervention modalities for health related problems of hispanics, health maintenance, timing and effectiveness of health education, and increasing public awareness of specific diseases and disabilities.

RESEARCH CAPABILITY

Public comment heavily endorsed the following two concepts:

- It is essential to train and provide research opportunities for young investigators. A renewed Federal commitment to support pre- and post doctoral research training is needed. Research careers must be made attractive to outstanding individuals, and promising new investigators with new and innovative ideas brought into the research community and provided support to replenish the scientific pool.
- Support for individuals and institutions upon which the continuity and productivity of research depends must be provided in a stable manner. Uncertainties and fluctuations in funding, radical short-term changes in policy, and poor timing in the training application process should be avoided.

Other recurring themes reflected in the public comments include the following:

- There is a need to attract, train, and retain physician scientists in research careers through providing opportunities for promising clinically-trained individuals with demonstrated aptitude for research to develop into independent investigators, by encouraging basic research scientists to enter clinically relevant fields of inquiry, and by examining policies and factors which may act as a deterrent to the recruitment of young clinical investigators.
- Support and research opportunities for minorities must be provided.
- Training programs, manpower needs and resources should be examined to determine requirements and shortage areas.
- Support for the purchase, construction and renovation of equipment and facilities is essential. There is a need to renew the physical research plant and offset the effects of inflation, increased costs of maintaining equipment, and requirements for expensive and sophisticated biomedical technology.

- Federal support policies should be designed to strengthen the institutions which perform research. Recognition should be given to the capabilities and contributions of all components of the health research community. (Specifically mentioned were the colleges and schools of public health, pharmacy, nursing, osteopathic medicine, and new and/or smaller institutions.) Attention should be given to the issue of indirect costs and the effects of administrative requirements and Federal regulations on the ability of institutions to perform their research mission.
- Interdisciplinary and collaborative research efforts should be encouraged both within institutions and among health professional schools, graduate schools and Federal and National laboratories.
- The Federal Government should maintain and strengthen its intramural research capabilities.

Additional suggestions and comments included the following:

- The National Service Award Act should be re-evaluated and possibly restructured to attract young researchers, and stipend levels and payback provisions should be re-examined closely.
- Provision of flexible institutional funds which permit new and/or smaller institutions to develop quality research programs and which may be used for start-up or transition support for exploratory research projects should be continued.
- Consideration should be given to providing longer-term support to highly qualified investigators.
- National workshops should be held to bring together (a) experienced investigators and post-doctoral candidates and (b) scientists in clinical medicine, basic science, and high technology to address specific areas of research.
- Consideration should be given to providing a separate budget for research equipment.
- The need for additional research training and expanded career opportunities was suggested in the following areas: behavioral science, health services, biostatistics, epidemiology, environmental health, nutrition, public health, urology, developmental neurosciences, anesthesiology, reproductive biology, preventive medicine, pediatrics, internal and family medicine, and education of medical students in sleep disorders and use of hypnosis.

UNIFYING CONCEPTS

This focus deals with concepts which underlie public funding of health research, interactions among the different parts of the research continuum as reflected in relative emphases and levels of investment, and relationships among the components of the public and private sectors which conduct and sponsor health research. The major themes reflected in the public comment are summarized under the following categories: public involvement in health research; investment and allocation within the health research continuum; DHEW missions, organization, and mechanisms for health research; and relationships with other sectors.

Public Involvement in Health Research

Major themes which addressed public expectations for health research and public involvement included the following:

- The public is a partner in the scientific enterprise. The success of the enterprise depends upon continued public support. In recent years, the social climate for the conduct of health research has changed to one of greater public accountability. The desire for rapid solutions to health problems and its translation through the political process have sometimes resulted in fluctuations in support and shifting priorities which reduce research productivity. There is a need to reaffirm the public commitment to health research.
- Efforts to develop effective public involvement in the formulation of research policy are required. The health research community should encourage efforts to increase public understanding of the scientific process, communicate the rationale underlying research funding decisions, and assume a responsibility to assist the public in setting realistic goals and time tables for research efforts. The Secretary's initiative was strongly endorsed as a means to provide for public involvement and participation.

Specific suggestions included the following:

- Public representation on advisory boards and councils should be increased and include individuals who suffer from health problems and representatives of voluntary groups.
- Special efforts are needed to assure that knowledgeable consent is obtained from minorities who participate in research activities.
- Congressional involvement and legislative mandates in establishing specific research priorities should be continued.

Investment and Allocation Within the Research Continuum

Public comments which addressed the relative emphasis and allocation of resources among the health research continuum reflected sharply contrasting views. The comments in general supported the concept of identifying policy objectives and broad areas of need to lend stability and coherence to the health research enterprise. Comments which addressed the desirability or feasibility of establishing specific support criteria or research priorities were disparate. Those perspectives and suggestions which were repeated by a number of organizations may be summarized as follows:

- The proportion of the total health dollar invested in health research should be increased.
- New monies should be made available to respond to newly perceived needs and new responsibilities. Reallocation and adjustments to correct past unbalances should be considered a partial solution; however, vital and productive ongoing research programs should not be curtailed.
- There is a need to stabilize annual fluctuations in funding levels and provide fiscal continuity for research efforts.
- The number of approved grant applications funded should be increased.
- Insufficient support has been provided to fundamental research.
- The population-based life-sciences should receive increased support.
- Federal funding policies should establish an appropriate balance among basic, applied, and targeted research.
- Peer review represents an effective means of assigning priorities to competing research activities. Research productivity is in large part a function of the number of people qualified to do quality research and the number of projects worth doing at a given time.
- Explicit criteria should be established to guide priority determinations among competing alternative expenditures.
- A number of factors were suggested as a basis to establish health research priorities. In many instances, the need to consider a number of interrelated factors was stressed. Factors identified included: economic indices and burden of illness measures (disease

incidence, mortality and morbidity, quality of life, age at onset, length of duration before death, social impairment, per capita measures), research opportunity, cost/benefit analysis, current state of the art, transferability of knowledge gained between diseases, public perception of relative importance of different health areas, prospects for achievement, and probable results estimated in quantitative terms.

DHEW Missions, Organization and Mechanisms for Health Research

Suggestions and views which were repeated with some frequency in the public comments included:

- While DHEW-funded research should contribute to the further development of the knowledge bases that support the health missions of the Department, the importance of biomedical and behavioral research as an independent mission should be recognized.
- The positive accomplishments and influences of the National Institutes of Health and the integrity of the agency's original mission - research and training - must be preserved. NIH should not assume responsibilities that are inappropriate for an agency with a primary research mission (such as direct standard setting or regulation and commitments to provide direct health care). To the extent that NIH is assigned new responsibilities, additional resources should be provided so as not to erode those committed to the agency's primary mission.
- The peer review mechanism should be retained and peer review or a comparable process applied to those programs where it is absent. Adverse factors or problems with the peer-review system should be carefully monitored and corrective action taken. Specific comments concerning the peer review process included the need for:
 - an appeal mechanism;
 - efforts to reduce the burdens on reviewers and applicants through increasing the number of study sections and reducing the length of applications;
 - modification of the Public Health Service Act to permit confidential, closed panel peer review of grant and contract applications;
 - orientation of review groups to the funding organization's total program and objectives;

- broadening the composition of advisory committees to encourage diversity, and
- more input from the scientific community and more rigorous attention to competence in the selection of advisory committee members.
- The grant application, renewal, and accounting processes should be streamlined and made more timely to reduce the burden on individuals and institutions receiving Federal support.
- Mechanisms of support should be tailored to the nature of the research effort. The investigator-initiated project grant is the most appropriate mechanism for fundamental research. Comparable evaluations for scientific excellence should be used for all mechanisms of support.

Additional, specific comments included:

- The role and authority of the Director, NIH, should be strengthened. Discretionary funds should be provided to pursue research leads and to promote interdisciplinary and collaborative efforts among Institutes.
- The ongoing reappraisal of the ADAMHA organization to provide flexibility to respond to increasing knowledge and new opportunities should be supported.
- Currently no system exists within the Department to respond in a timely fashion to support research on new or emerging public health problems; provision of funds for extramural research to the Center for Disease Control could fill this need.
- A long-range NIH policy-making body should be established to review recommendations of inter-Institute coordinating committees.
- Special institutional frameworks should be developed to address research programs in newly emerging or novel problem sectors.
- Department health research capabilities should be centralized under a Coordinator.
- Grant applications should not be subject to review or control by health system agencies although information copies should be provided.

Relationships with Other Sectors

A recurring theme in the public comment was the need for the Department to examine existing relationships, consider the contributions and resources, strengthen cooperative efforts, and explore new methods of interaction with and among Federal agencies, private industry, voluntary organizations, State and local governments, academic institutions and health professional schools, and the international sector in health research.

Additional comments included the following:

- As part of the effort to maintain and strengthen the partnership between the Federal government and industry in the area of health research, an examination and reappraisal of existing patent policy are needed.
- The Federal government should take responsibility for encouraging private firms, through subsidies or other means, to develop drugs for the control of low-incidence disorders.
- There is a need to provide incentives, such as funding scientific consortia, to promote improved interactions among the public and private sectors involved in health research.
- Cooperation between the Federal government and voluntary health organizations should be strengthened. The Federal government should take the lead and provide guidance to effect consolidation of voluntary groups concerned with the same or similar health problems.
- There is a need for better coordination among Federal agencies which support research in specific areas particularly when there is overlapping jurisdiction and authorities. Specifically mentioned was the need for improved coordination among Federal agencies with an interest in hearing and speech disorders.
- Federal and State agencies should work together in identifying priorities for applied health research.

ATTACHMENT #3

ORGANIZATIONS PROVIDING COMMENTS ON HEALTH RESEARCH PRINCIPLES
FOR THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

The Alan Guttmacher Institute
Albert Einstein College of Medicine Cancer Research Center
Alternatives to Abortion International
American Academy of Nurses
American Academy of Physician Assistants
American Association for Cancer Research
American Association of Colleges of Osteopathic Medicine
American Association for Dental Research
American Association of Dental Schools
American Board of Medical Specialties
American Brittle Bone Society, Inc.
American College of Cardiology
The American College of Obstetricians and Gynecologists
American Dental Hygienists' Association
American Enterprise Institute for Public Policy Research
American Federation for Clinical Research
American Foundation for the Blind, Inc.
American Heart Association
American Industrial Hygiene Association
American Institute of Biological Sciences
American Medical Association
American Narcolepsy Association
The American National Red Cross
American Nurses' Association, Inc.
American Pharmaceutical Association
American Physical Therapy Association
American Psychiatric Association
American Psychological Association
The American Society for Clinical Hypnosis
American Society of Hematology
American Society of Law and Medicine
American Society of Plant Physiologists
American Society for Microbiology
American Sociological Association
American Statistical Association of America, Inc.
American Thoracic Society
American Type Culture Collection
American Urological Association, Inc.
Amyotrophic Lateral Sclerosis Society of America
The Andrew W. Mellon Foundation

Arthritis Foundation
Association of American Medical Colleges
Association for Children with Learning Disabilities
Association of Schools of Public Health
Association of Sleep Disorders Centers
Association of University Anesthetists
Blue Cross - Blue Shield
California Health and Welfare Agency
California Legislature Assembly Select Committee on Genetic Diseases
Childrens Hospital Medical Center
Citizens' Committee for the Conquest of Cancer
The Commonwealth Fund
Conference of State and Territorial Epidemiologists
Cooley's Anemia Foundation, Inc.
Cystic Fibrosis Foundation
Delegation for Basic Biomedical Research
Down's Syndrome Congress
Duke-Watts Family Medicine Program
Epilepsy Foundation of America
Federation of American Societies for Experimental Biology
Fight for Sight, Inc.
Group Health Association of America, Inc.
Hereditary Disease Foundation
Institute of Food Technologists
International Chiropractors Association
International Committee Against Mental Illness
Joslin Diabetes Foundation, Inc.
Latino Caucus American Public Health Association
The Living Bank
Maternity Center Association
Muscular Dystrophy Association
National Amyotrophic Lateral Sclerosis Foundation, Inc.
National Association for Hearing and Speech Action
National Black Nurses' Association
National Environmental Health Association
The National Foundation March of Dimes
National Huntington's Disease Association
National Lupus Erythematosus Foundation, Inc.
National Multiple Sclerosis Society
National Paraplegia Foundation
National Pituitary Agency
National Right to Life Committee, Inc.
Pan American Health Organization
Parenteral Drug Association
Pharmaceutical Manufacturers Association

Population Reference Bureau, Inc.
Reticuloendothelial Society
Retinitis Pigmentosa Foundation
The Robert Wood Johnson Foundation
Sex Information and Education Council of the United States
The Society for Investigative Dermatology, Inc.
The Society of Teachers of Family Medicine
State Mental Health Research Directors
State University of New York at Stonybrook, Health Sciences Center
Southern Regional Education Board Commission on Mental Health and Human Services
Tuberous Sclerosis Association of America, Inc.
Tourette Syndrome Association
Tufts University Cancer Research Center
United Automobile, Aerospace and Agricultural Implement Workers of America
United States Conference of City Health Officers
University of Maryland Hospital - Blood Bank Transfusion Service
University of Utah College of Medicine, Department of Neurology
Visiting Nurse Service of Summit County, Inc.
W. K. Kellogg Foundation
Worcester Foundation for Experimental Biology

ATTACHMENT #5

CONFERENCE LOGISTICS AND ADMINISTRATIVE INFORMATION
FOR
NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

Date, Location, Time: The Conference will convene at the National Institutes of Health, Jack Masur Auditorium, Clinical Center (Building 10), 9000 Rockville Pike, Bethesda, Maryland. Registration is at 8:30 a.m.; the Conference will begin at 9:00 a.m., Tuesday, October 3rd and end at approximately 4:00 p.m., Wednesday, October 4th.

Parking: Parking Lot 41-B has been reserved during the days of the Conference for participants who drive. Shuttle bus service will be available from this parking lot to Building 10, Clinical Center (see attached map).

Registration: Registration will take place from 8:30 - 9:00 a.m. in the lobby adjacent to the Masur Auditorium, Building 10, Clinical Center. Due to the construction of the Ambulatory Care Research Facility, the rear entrance of Building 10 must be used. There will be two tables for general registration. At the time of registration, the following materials will be distributed:

- Identification badges required for admission to all plenary and Panel sessions;
- Schedule of the order of public witnesses to testify before each Panel;
- Completed roster of Panel members; and
- Indexed copy of all suggestions on which the summary of public comments contained in Attachment #3 is based.

(Note: Those individuals who have pre-registered for the Conference and are unable to attend on October 3rd should register between 8:30 - 9:00 a.m. on October 4th at the lobby adjacent to the Masur Auditorium.)

Opening and Closing Plenary Sessions: These sessions will be held in the Masur Auditorium, Building 10, Clinical Center. All registered participants will be able to attend the plenary sessions. In the event the auditorium is filled to capacity, remote viewing of the plenary sessions will be available on the 14th floor of Building 10. Seats at these sessions have been reserved for Panel members, Institute of Medicine committee members, the press, and a limited number of DHEW agency staff. Seating in the auditorium will be based upon registration time.

Panel Sessions: The location of all Panel sessions is identified on the Program (Attachment #1) and on the accompanying sheet, along with telephone numbers for the receipt of messages. All Panel sessions are open to registered Conference participants. Identification badges must be displayed to gain entrance to these sessions. Please note that two Panels - Fundamental Research and Clinical Applications and Health Services Research - will be split the morning and afternoon of October 3rd to receive public testimony. These Panels will remain split for a short period of time after dinner on October 3rd to summarize, then reconvene as single, full Panels that evening in conference rooms 6 (Fundamental Research) and 10 (Clinical Applications and Health Services Research) in Building 31.

Seating capacity at the Panel locations is as follows:

- Panel 1 - Fundamental Research

- Session A: Conference Room 6 - 110 individuals
 - Session B: Conference Room 7- 40 individuals

- Panel 2 - Clinical Applications and Health Services Research

- Session A: Conference Room 10 - 100 individuals
 - Session B: Conference Room 8 - 40 individuals

- Panel 3 - Health Regulation and Promotion
Conference Room 4 - 55 individuals
- Panel 4 - Research Capability
14th Floor, Building 10, Clinical Center - 220
individuals
- Panel 5 - Unifying Concepts
3rd Floor, Building 1, Wilson Hall - 200 individuals

At each Panel session the morning and afternoon of October 3rd, 10 seats have been reserved for registered participants who will be providing testimony. It will be necessary to be seated according to the Panel testimony schedule and for seats to be released to other witnesses as testimony progresses. To ensure this process runs smoothly, all participants registered to testify before a Panel must check-in with the receptionist at the Panel site and be shown to reserved seating. Once testimony is completed, these seats will be released.

Also a very limited number of seats will be reserved at each Panel session on both days for the Institute of Medicine committee representatives and DHEW agency staff. The balance of the space will be available for registered Conference participants, displaying identification badges, to observe the Panel sessions.

Public Testimony: For reasons described in the cover memorandum, all individual public testimony before each Panel will be limited to five minutes. Panel Chairpersons have been instructed to adhere to this schedule. This schedule will not permit the showing of any slides or other audiovisual materials.

Individuals pre-registered to testify must submit a typed copy of their testimony. This is to be submitted at the receptionist desk located at each Panel site immediately after the opening plenary session. Please indicate your name, institutional affiliation and the Panel to which your comments are addressed on the top of the first page of your testimony. For those of you who have registered to testify before more than one Panel, please begin your testimony before each Panel on a new page and repeat the identification at the top. Testimony must be deposited at the appropriate Panel site, but for those of you testifying before more than one Panel, all testimony may be deposited at a single site. Staff will make it available to the appropriate panel.

Witnesses who wish to provide more extensive remarks for the public record may submit written comments which should be forwarded to:

Mr. Kurt Habel
Chief, Program Planning Branch
D.P.A., O.P.P.E.
Office of the Director
National Institutes of Health
Building 1, Room 205
Bethesda, Maryland 20014

Written comments received by October 20, 1978 will be incorporated as part of the Conference proceedings.

Refreshments and Meals: Refreshments and meals are available each day at the following locations:

Building 10 - (Clinical Center)
Cafeteria

7:30 a.m. to 9:00 a.m. - breakfast
11:00 a.m. to 2:00 p.m. - lunch
4:30 p.m. to 8:30 p.m. - dinner
(open all day for refreshments)

Building 1 Cafeteria

7:30 a.m. to 8:30 a.m. - breakfast
11:30 a.m. to 1:30 p.m. - lunch

Building 31 Cafeteria

7:30 a.m. to 8:30 a.m. - breakfast
11:00 a.m. to 1:30 p.m. - lunch

Tape Recording: In order to prepare an official transcript of the Conference proceedings and to document questions and answers for use in drafting the Conference report, all plenary and Panel sessions will be recorded.

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES
October 3-4, 1978

Panel sessions addressing major foci of the Conference convene at the following locations:

PANEL ON FUNDAMENTAL RESEARCH

- | | |
|---|--|
| A | Conference Room 6
Building 31 C Wing 6th floor
Telephone for messages:
Area Code 301 - 496-6161 |
| B | Conference Room 7
Building 31 C Wing 6th floor
Telephone for messages:
Area Code 301 - 496-6161 |

PANEL ON CLINICAL APPLICATIONS AND
HEALTH SERVICES RESEARCH

- | | |
|---|---|
| A | Conference Room 10
Building 31 C Wing 6th floor
Telephone for messages:
Area Code 301 - 496-6161 |
| B | Conference Room 8
Building 31 C Wing 6th floor
Telephone for messages:
Area Code 301 - 496-6161 |

PANEL ON HEALTH REGULATION AND PROMOTION

Conference Room 4
Building 31 A Wing 1st floor
Telephone for messages:
Area Code 301 - 496-1830

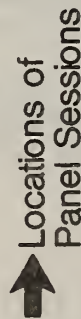
PANEL ON RESEARCH CAPABILITY

Building 10 - Clinical Center
14th Floor
Telephone for messages:
Area Code 301 - 496-1450

PANEL ON UNIFYING CONCEPTS

Building 1 - Wilson Hall 3rd floor
Telephone for messages:
Area Code 301 - 496-2521

Attached map identifies locations of buildings.



Conference
Parking Lot

- 2 LAB - NAT INST OF ARTHRITIS, METABOLISM AND DIGESTIVE DISEASES
- 3 LAB - NATIONAL HEART & LUNG INSTITUTE
- 4 LAB - NAT INST OF ARTHRITIS, METABOLISM AND DIGESTIVE DISEASES
- 5 LAB - NAT INST OF ALLERGY & INFECTIOUS DISEASES
- 6-8A LAB - NAT INSTS OF NICHD, NEI & NIAMD
- 7 LAB - NAT INST OF ALLERGY & INFECTIOUS DISEASES
- 8 LAB - NAT INST OF NEUROLOGICAL DISEASES AND STROKE, CANCER, ALLERGY & INFECTIOUS DISEASES
- 9 LAB - NAT INST OF MENTAL HEALTH, NAT INST OF NEUROLOGICAL DISEASES AND STROKE, NAT EYE INSTITUTE
- 10 CLINICAL CENTER
- 10A SURGICAL WING
- 11 BOLLER & REFRIGERATION PLANT
- 2 FINE DEPT. GARAGE & OCRT COMPUTER CENTER AND OFFICES
- 24 OFFICES, OCRT, DES, DRS & OPPE
- 12B DIVISION OF COMPUTER RESEARCH TECHNOLOGY
DES, DRS, CC & DRS
- 4-6G. ANIMAL BUILDINGS
- 5A-1 OFFICERS' QUARTERS
- 15K WILSON HOUSE - N1N1
- 6 STONE HOUSE - FIC
- 16A OFFICES - FIC
- 7 PEP CO SWITCHING STATION
- 8 LAB & ANIMAL BLDG - NICNO
- 20 APARTMENT HOUSE
- 71 SOTOPE LABORATORY - DRS
- 22 GROUND'S MAINTENANCE - DES
"TRANSPORTATION DAS
- 25 CHEMICAL STORAGE
- 26 CHEMICAL DISPOSAL
- 28 ANIMAL BUILDING & KENNELS - DRS
- 25 29A BUREAU OF BIOLOGICS - FOA
- 10 LAB - NAT INST OF DENTAL RESEARCH
- 31 GENERAL OFFICE BLDG
- 32 GREENHOUSE - N1N1
- 34 CHILLED WATER PLANT
- 35 CAFETERIA - CHILD CARE CENTER
- 36 LAB - NAT INST OF DENTAL HEALTH, NEUROLOGICAL DISEASES & STROKE
- 37 LAB - NATIONAL CANCER INSTITUTE
- 38 NATIONAL LIBRARY OF MEDICINE
- 41 FREEMAN HALL - ISOLATION FACILITY - NCI
- 46 ELECTRICAL SUB-STATION

MULTI LEVEL PARKING

7-2. CHEMICAL STORAGE



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

September 15, 1978

MEMORANDUM TO: Professional Societies, Health Organizations and
Individuals Requesting Pre-Conference Material

SUBJECT: Pre-Conference Draft DHEW Health Research Principles

Joseph A. Califano, Jr., the Secretary of the Department of Health, Education, and Welfare has asked that I send to you the pre-Conference material developed for the National Conference on Health Research Principles, to be held at the National Institutes of Health in Bethesda, Maryland, on October 3-4. Those of you who have requested a copy of the pre-Conference principles that have been developed will find this material in Attachment #2, with additional suggestions in Attachment #3 and #4. This material will also be useful to those of you who have sent in registration cards indicating you cannot attend the Conference but plan to submit comments for consideration at that time.

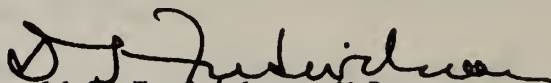
Your comments are invited. For comments to be considered at the Conference, they must be received no later than Friday, September 29. Comments received after that date will be considered in preparing the final report. All comments should be structured around the five major substantive areas to be addressed at the Conference: Fundamental Research, Clinical Applications and Health Services Research, Health Regulation and Promotion, Research Capability and Unifying Concepts. Please give your name, institutional affiliation and the Panel to which your comments are addressed on the top of the first typed page of your comments. Please begin comments on each major substantive area on a new page and repeat the identification at the top. Send your comments directly to:

Mr. Kurt Habel
Chief, Program Planning Branch
D.P.A., O.P.P.E.
Office of the Director
National Institutes of Health
Building 1, Room 205
Bethesda, Maryland 20014

The Conference will result in a draft report of health research principles for the Department. This report will also be distributed widely for public comment and will form the basis for the later development of a multi-year strategy for health research in the Department. This report will automatically be sent to you for comment. In addition, the Secretary has asked the Institute of Medicine, National Academy of Sciences, to evaluate this draft report.

Page 2

Both Secretary Califano and I wish to express our appreciation to you for your interest in and contributions to this initiative and look forward to additional suggestions from you as this process moves ahead.


Donald S. Fredrickson, M.D.
Director

Enclosures (Not Included)



highlights

SUNSHINE ACT MEETINGS 42100

NATIONAL PORT WEEK

Presidential proclamation 41941

FEDERAL EMERGENCY MANAGEMENT AGENCY

Reorganization plan 41943

FAMILY PLANNING SERVICES

HEW/PHS proposes changes in regulations governing the award and administration of grants; comments by 11-3-78 42019

BLACK LUNG BENEFITS

Labor Benefits Review Board issues rules revising rules of practice and procedure relating to implementation of the Black Lung Benefits Reform Act of 1977 and the Black Lung Benefits Revenue Act of 1977; effective 10-19-78 (Part IV of this issue) 42144

TRANSPORTATION FOR ELDERLY AND HANDICAPPED PERSONS

DOT/UMTA rules to amend Transbus procurement requirements to require ramp or lift at front door; effective 9-14-78 . 41937

DISASTER LOANS

SBA issues proposal setting forth procedures for requesting disaster declarations and time limit for request; comments by 11-20-78 42016

COMMUNITY DEVELOPMENT PROCEDURES BLOCK GRANT PROGRAM

HUD/Secy proposes to amend and revise environmental review procedures; comments by 10-19-78 (Part VIII of this issue)..... 42220

ANIMAL WELFARE ACT

USDA/APHIS proposes standards and regulations for the humane handling, care, treatment, and transportation of marine mammals; comments by 11-20-78 (Part VII of this issue) .. 42200

PRIVACY ACT

CSA and Labor publish systems of records..... 42116

PHYSICIAN LABELING FOR ANTIPSYCHOTIC DRUGS

HEW/FDA extends time for comments on precaution statement; comments by 10-18-78..... 42042

SURFACE COAL MINING AND RECLAMATION OPERATIONS

Interior/OSMRE announces public briefing on 9-22-78 on proposed permanent program regulations 42018

cations and action documents, including substantive policy review and followup to insure timely and appropriate action and clearances; (6) tracks and reports on progress in meeting program objectives; (7) manages the administrative aspects of OHMO contract activities; and (8) develops and monitors manpower management and work planning systems for the HMO central office staff.

Division of Development (HA21). (1) Encourages the development and expansion of HMO's, in coordination with the Division of Program Promotion, by providing and monitoring grants, contracts, loans, and loan guarantees to public, nonprofit, and private entities to pursue HMO planning and development activities; provides advice and assistance as needed to HMO's and entities seeking HMO status to enhance developmental activities; (2) establishes standards and procedures for HMO grant reviews and awards; (3) establishes standards and procedures for all loan applications, awards, and reviews; (4) directs and coordinates the HMO grant and loan management activities in the headquarters/regional offices; (5) conducts regular analyses for adequacy of developmental activities for individual HMO projects and prepares quarterly reports projecting the potential for success of developmental activities for budget planning purposes; (6) analyzes needs and develops forecasts for the national grant and loan/loan guarantee programs; and (7) performs congressional, HEW, and other intergovernmental liaison related to development activities.

Division of Qualification (HA22). (1) Establishes qualification standards, and determines the acceptability of entities seeking to become "qualified HMO's"; (2) refines review procedures as necessary to facilitate the qualification process; (3) coordinates and insures consistency of regional office activities related to the qualification process; (4) assists the Office of the General Counsel in the development of legal actions concerning HMO qualification status; (5) performs congressional, HEW, and other intergovernmental liaison related to qualification activities; (6) provides technical assistance to HMO's developed through public and private resources, in the fields of medical care organization, quality assurance, financial management, marketing, legal assistance, and health care administration; (7) develops policy and regulations related to HMO qualification; (8) evaluates impact of policies, legislation, and regulation on ability of projects to become qualified; and (9) provides guidance as to interpretation of policy guidelines and regulations related to qualification.

Division of Program Promotion (HA23). (1) Develops national promotion strategies and provides assistance to Federal, State, public, and private agencies and organizations to encourage the identification of potential areas for HMO development; (2) analyzes national needs to assess potential HMO development geographically and by sponsor; (3) generates an annual national HMO report to Congress; (4) coordinates Federal promotional activities with national professional and trade organizations, and business and labor communities to promote effective joint actions beneficial to HMO development; (5) develops, edits, and evaluates promotional educational and guidance materials and information pertinent to communicating and understanding HMO concepts, operations, and performance; (6) coordinates publication and distribution of public information materials and reports; and (7) coordinates promotional activities performed by regional offices.

Division of Compliance (HA24). (1) Assures the continuing compliance of HMO's with the statutory requirements of the HMO law; (2) assures compliance by employers with a mandatory offering of the HMO alternative in employee health benefits plans; (3) assists the Office of the General Counsel in the development of legal actions against HMO's and employers considered not to be in compliance with applicable standards and regulatory requirements; (4) reviews standards, procedures, and reporting requirements for monitoring of HMO's that receive financial assistance under grants, loans, and loan guarantees; (5) establishes and updates standards and procedures for compliance monitoring of qualified HMO's, and prepares status reports for internal and external use; (6) assures consistency of regional office activities related to compliance monitoring; (7) assures compliance by loan recipients with the legislative requirement for fiscal viability; (8) utilizes computerized data systems to maintain and monitor national HMO activity and statistics; (9) establishes and maintains liaison with concerned State and local regulatory and monitoring agencies; (10) provides technical assistance to qualified HMO's developed through public and private resources, in the fields of medical care organization, quality assurance, financial management, marketing, legal assistance, and health care administration; (11) develops policy and regulations related to HMO compliance; (12) evaluates impact of policy, legislation, and regulation on ability of qualified HMO's to remain in compliance; and (13) provides guidance as to interpretation of policy

guidelines and regulations related to HMO compliance.

Dated: September 8, 1978.

LEONARD D. SCHAEFFER,
Assistant Secretary for
Management and Budget

(FR Doc. 78-26228 Filed 9-18-78; 8:45 am)

[4110-12]

Office of the Secretary

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

Meeting

Notice is hereby given of the National Conference on Health Research Principles to be held on October 3-4, 1978, at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Md.

The National Conference is part of a new open process which has been initiated by the Secretary of Health, Education, and Welfare, and which is designed to solicit public advice in developing principles of a multiyear strategy to guide DHEW health research activities. All agencies engaging in health research within the Department, the Office of the Assistant Secretary for Health, and other Department staff offices are involved in the Secretary's initiative. The Director of the National Institutes of Health has been asked to take the lead in coordinating this effort.

Approximately 1,000 professional societies and health organizations as well as other Federal departments and agencies have been asked for their suggestions on the principles the Department should adopt. The comments received from the health community, the public, and other Federal agencies have been considered in formulating a statement of proposed DHEW health research principles to be presented to the National Conference.

The Conference will be open to the public and will serve both as a forum to elicit additional public advice and to revise the proposed DHEW principles based on a consideration of oral and written public testimony. The Conference will be structured around five major areas: Fundamental research, clinical applications and health services research, health regulation and promotion, research capability, and unifying concepts. Five panels will receive and consider testimony from preregistered witnesses on these five focuses. There will be two brief plenary sessions to open and close the Conference. Attendance by the public will be limited by the space available. The Conference will result in a draft report of health research principles for the Department. This report will be distributed widely for public comment.

and will form the basis for the later development of a multiyear strategy for health research in the Department.

Members of the public are invited to provide written comments on the statement of proposed DHEW health research principles which will be available in mid-September. Comments received by September 29 will be considered during the Conference. Written comments received after September 29 will be incorporated as part of the public record and considered during subsequent stages of the process. Individuals who wish to receive a copy of the statement of proposed DHEW health research principles for purposes of providing written comments or who want further information on Conference arrangements may write or telephone Mr. Kurt Habel, Office of the Director, National Institutes of Health, Building 1, Room 205, Bethesda, Md. 20014, 301-496-1454.

Dated: September 11, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education,
and Welfare.

[FR Doc. 78-26261 Filed 9-18-78; 8:45 am]

[4110-35]

Health Care Financing Administration

PHARMACEUTICAL REIMBURSEMENT BOARD

Proposed MAC's and Announcement of Public Hearing

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Correction of notice.

SUMMARY: In FR document No. 78-24487, appearing in the FEDERAL REGISTER on August 31, 1978, at page 38941, an error occurred in the proposed Maximum Allowable Cost (MAC) limit on amoxicillin oral suspension 250mg/5cc. The proposed limit should read \$.0465 instead of \$.0461.

FOR FURTHER INFORMATION CONTACT:

Peter Rodler, Executive Secretary,
Pharmaceutical Reimbursement
Board, 3076 Switzer Building, 330 C
Street SW., Washington, D.C. 20201,
202-472-3820.

Dated: September 15, 1978.

PETER RODLER,
Executive Secretary
Pharmaceutical Reimbursement
Board.

[FR Doc. 78-26465 Filed 9-18-78; 10:27 am]

[4210-01]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. D-78-533]

ASSISTANT SECRETARY FOR NEIGHBORHOODS, VOLUNTARY ASSOCIATIONS AND CONSUMER PROTECTION

Delegation of Authority

AGENCY: Department of Housing and Urban Development.

ACTION: Delegation of authority.

SUMMARY: The Secretary is delegating to the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection all of her authority under the Lead Based Paint Poisoning Prevention Act, except the Secretary's authority with respect to research, which shall be exercised by the Assistant Secretary for Policy Development and Research in consultation with the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

EFFECTIVE DATE: September 2, 1977.

FOR FURTHER INFORMATION CONTACT:

Rebecca Johnson, Office of the Deputy Assistant Secretary for Regulatory Functions, Department of Housing and Urban Development, Room 3234, Washington, D.C. 20410, telephone 202-755-6526.

SUPPLEMENTARY INFORMATION: Under sections 301, 302, and 401 of the Lead Based Paint Poisoning Prevention Act, as amended, 42 U.S.C. 4801 et seq., the Secretary of Housing and Urban Development is required to carry out research to determine the nature and extent of lead paint poisoning in the United States, to establish procedures to eliminate the hazards of lead-based paint poisoning in certain existing housing, and to take steps and to impose such conditions as may be necessary to prohibit the use of lead-based paint in residential structures constructed or rehabilitated by the Federal Government or with Federal assistance. The primary responsibility for this program has to date been vested in the Assistant Secretary for Policy Development and Research.

With the establishment of the Office of the Deputy Assistant Secretary for Regulatory Functions under the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection, the Secretary has determined that the responsibility for assuring the implementation of the requirements of the Act should be carried out by the Assistant Secretary for Neighborhoods, Voluntary Associ-

ations and Consumer Protection. However, since research remains a major function of the Secretary under the Act, and since all research done by the Department of Housing and Urban Development is carried out under the auspices of the Assistant Secretary for Policy Development and Research, the Secretary has determined that the responsibility for carrying out required research shall be vested in the Assistant Secretary for Policy Development and Research in consultation with the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

Accordingly, the Secretary delegates authority as follows:

SECTION A. *Authority delegated.* The Secretary delegates to the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection all of her power and authority under the Lead Based Paint Poisoning Prevention Act, as amended, 42 U.S.C. 4801 et seq., except that the Secretary directs that her authority under section 301(a) of the Act, 42 U.S.C. 4821(a) shall be exercised by the Assistant Secretary for Policy Development and Research, in consultation with the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

SEC. B. *Authority excepted.* The power to sue and be sued is excepted from the authority delegated under section A.

SEC. C. *Authority to redelegate.* The Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection is authorized to redelegate to employees of the Department and to agents of the Department any of the power and authority delegated under section A of this delegation except the power to issue rules and regulations.

(Sec. 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).)

Issued at Washington, D.C., September 11, 1978.

PATRICIA ROBERTS HARRIS,
Secretary of Housing and
Urban Development

[FR Doc. 78-26255 Filed 9-18-78; 8:45 am]

[4310-84]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM 34437 and 34495]

NEW MEXICO

Applications

SEPTEMBER 8, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as

HEW



NEWS

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOR IMMEDIATE RELEASE
Friday, September 29, 1978

Kurt Habel — (301) 496-1454
Guy Moore — (301) 496-2535

A National Conference to help develop principles for funding biomedical research will be held next week at the National Institutes of Health, Secretary Joseph A. Califano, Jr., announced today.

Set for October 3-4, 1978, the National Conference on Health Research Principles is a key step in the Department's effort to provide strong and consistent support for research, add greater balance to all health research activities, and set research priorities which reflect national needs.

"In an era in which resources for research are limited, we must develop an overall strategy for choosing how to spend the Federal research dollar," the Secretary said. "A multi-year plan should allow us to reduce annual fluctuations in research budgets that make rational research planning so difficult."

Last fall, President Carter ordered a comprehensive review of Federal support for basic research, and directed that a new emphasis be placed on basic research in Federally-supported science programs.

In an April speech before the Annual Meeting of the American Federation for Clinical Research, Secretary Califano announced the initiation of a new, open process including a national conference to set principles to guide the allocation of limited government health research dollars. Hundreds of professional societies and health organizations have been canvassed for their ideas and suggestions and other Federal Departments and agencies have also been invited to participate in the process.

A Departmental Steering Committee chaired by Dr. Donald S. Fredrickson, the Director of the National Institutes of Health, is overseeing this process. HEW agencies and organizations that engage in health research activities are now developing draft principles.

The comments received from the health community, the public, and other Federal agencies will be considered in formulating a statement of proposed HEW health research principles to be presented to the National Conference. The results of the Conference will be published to solicit additional public comment.

In his April speech, Secretary Califano suggested what some of these principles might be:

- o HEW supported research must be more effectively oriented to develop knowledge bases that support all the health missions of the Department -- prevention, delivery, regulation, standard-setting and cost control.
- o Federal efforts should maintain, at a high level, and enhance our support for fundamental research into biology and behavior.
- o Basic research must be accompanied by vigorous, thoughtful and, where appropriate, interdisciplinary applications.

"We must shape a process that will produce a strengthened research enterprise which both pursues knowledge openly and freely, for its own sake, but also serves the health needs of the American people," the Secretary said.

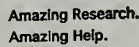
Additional information about the conference may be obtained from Kurt Habel, National Institutes of Health, Building 1, Room 205, Bethesda, Maryland 20014, (301) 496-1454.

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